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(54) **PATIENT-SPECIFIC HUMERAL GUIDE DESIGNS**

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CPC ***A61B 17/1778*** (2016.11); ***A61B 17/15*** (2013.01); *A61B 2034/108* (2016.02)

(58) **Field of Classification Search**

CPC A61B 17/1778; A61B 17/15; A61B 17/17; A61B 17/1739; A61B 2034/108

See application file for complete search history.

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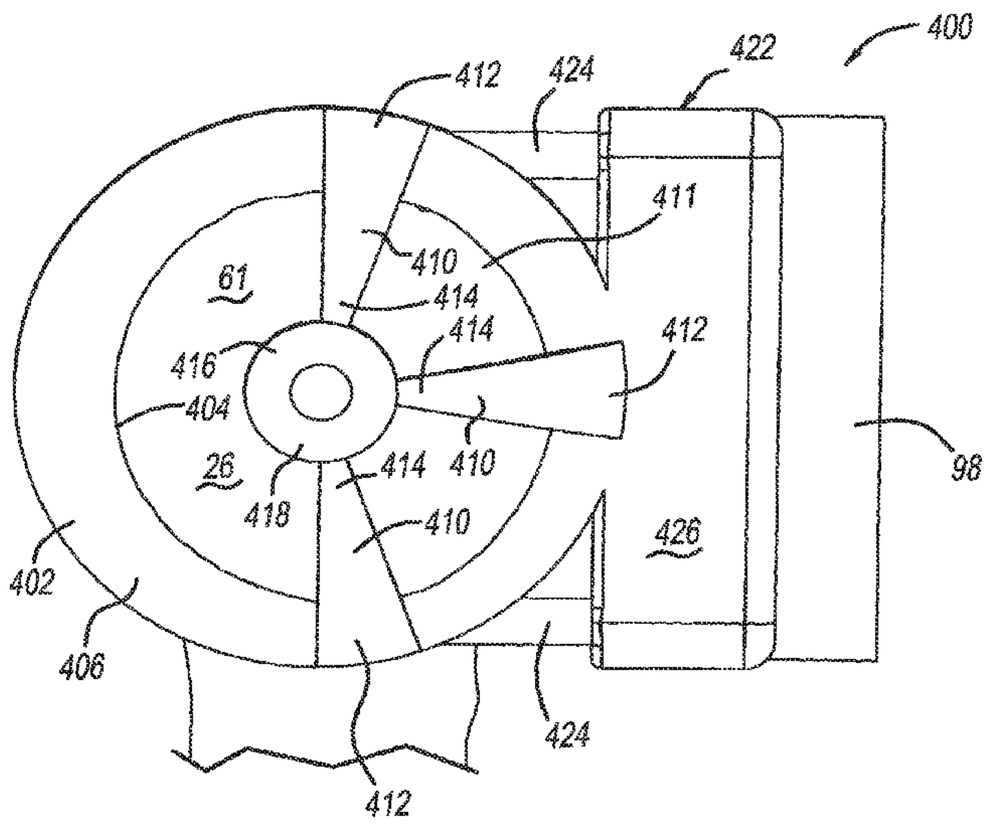
(57) **ABSTRACT**

A humeral cut guide member for resectioning or resurfacing a humeral head, including a bone-engagement member including a first patient-specific bone-engagement surface that is complementary and made to substantially mate and nest in only one position on a specific patient's humeral head; a registration member connected to the bone-engagement member including a second patient-specific bone engagement surface that is sized and made to substantially mate and nest in only one position with the specific patient's bicipital groove; and a cut guide plate connected to the bone-engagement member and defining an elongated slot.

19 Claims, 11 Drawing Sheets



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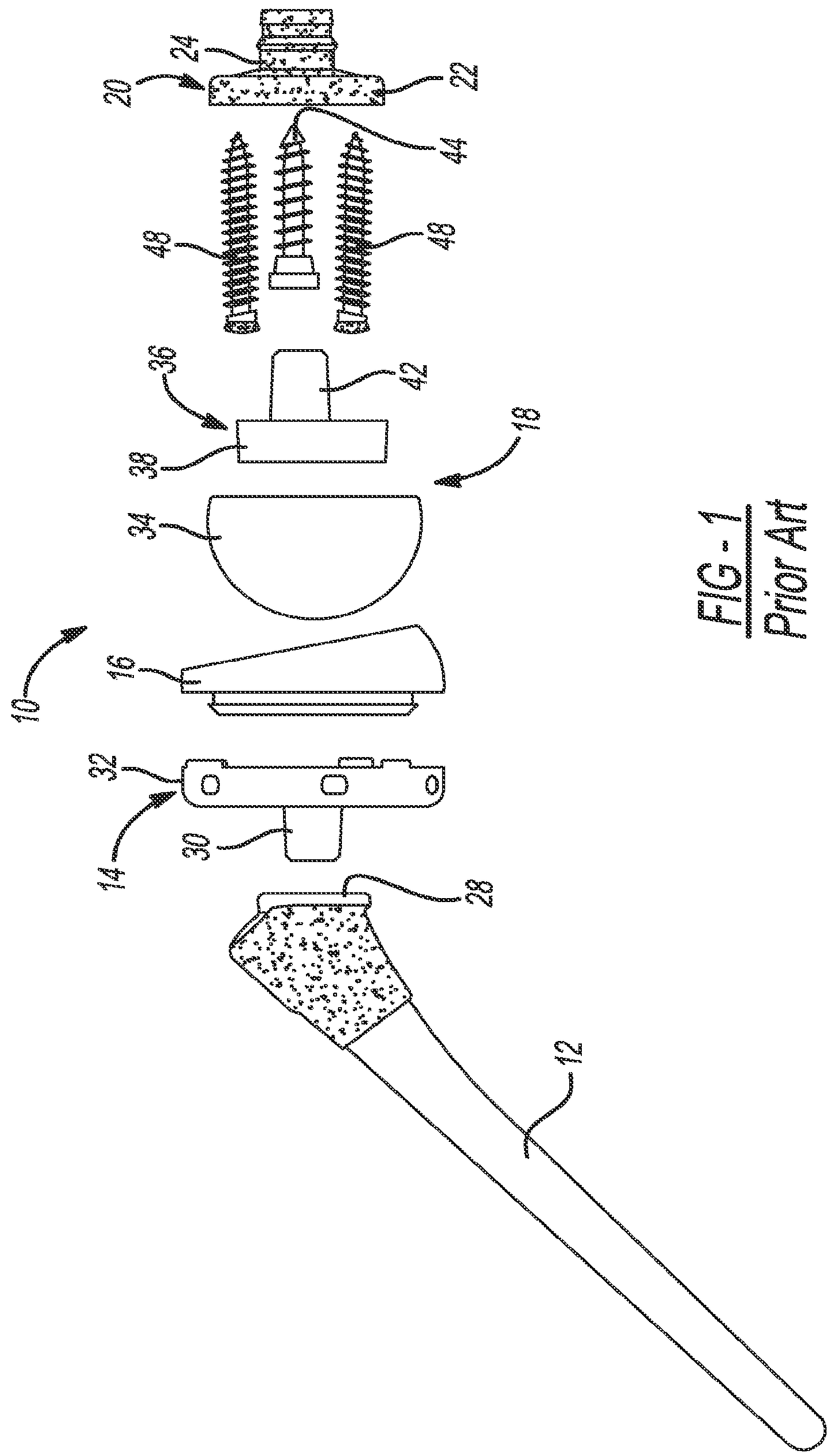

FIG - 1
Prior Art

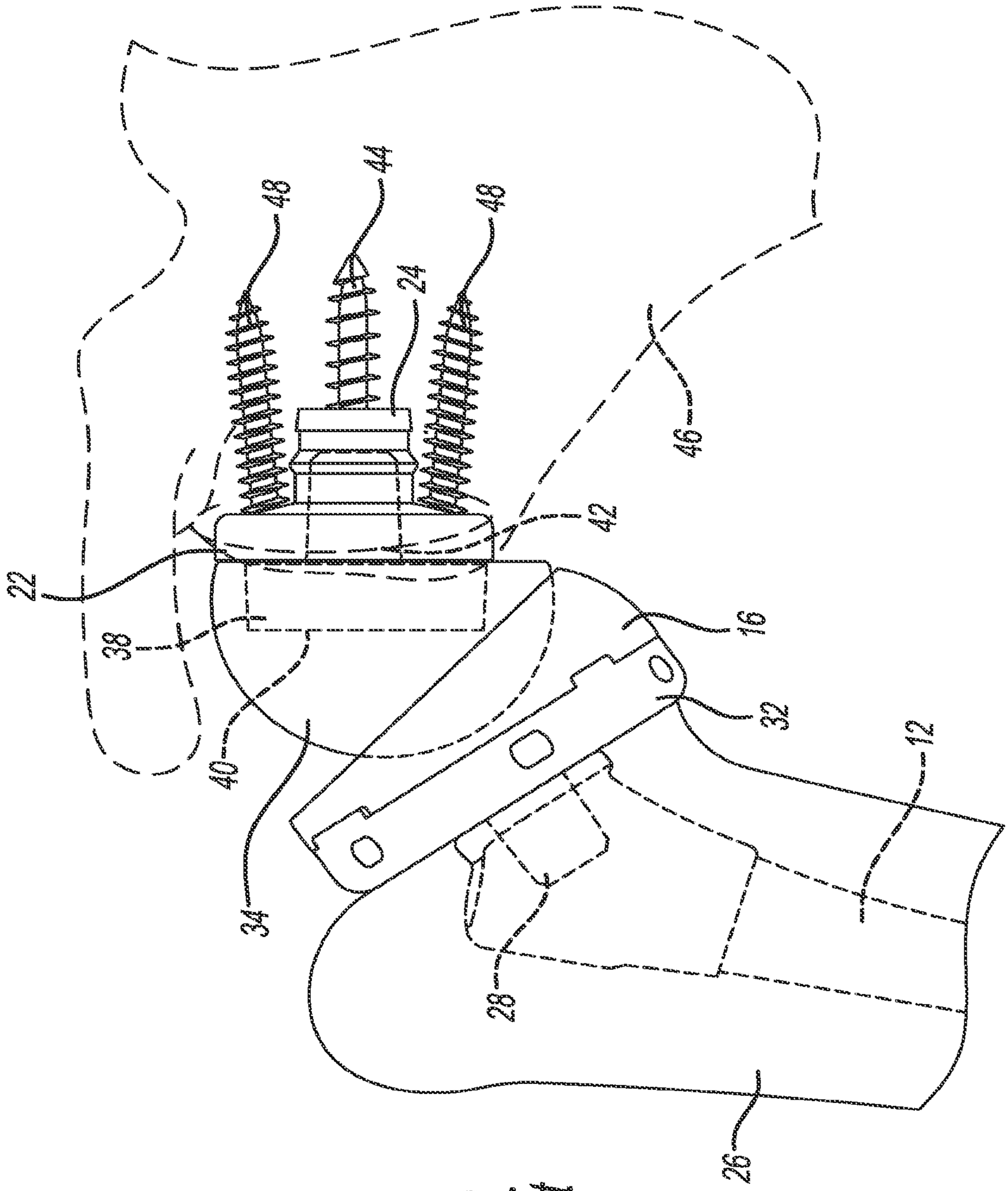

FIG - 2
Prior Art

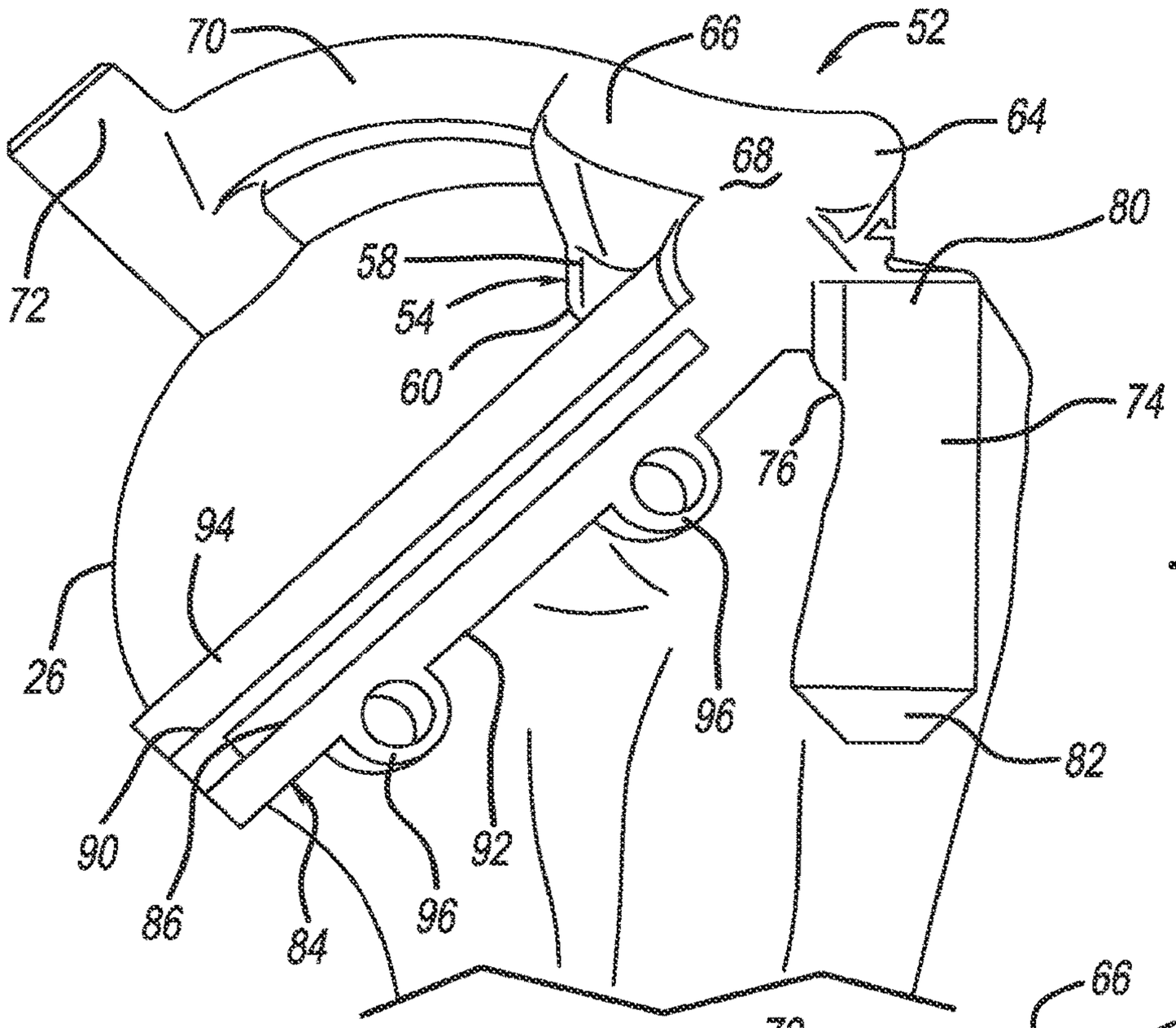
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FIG - 3

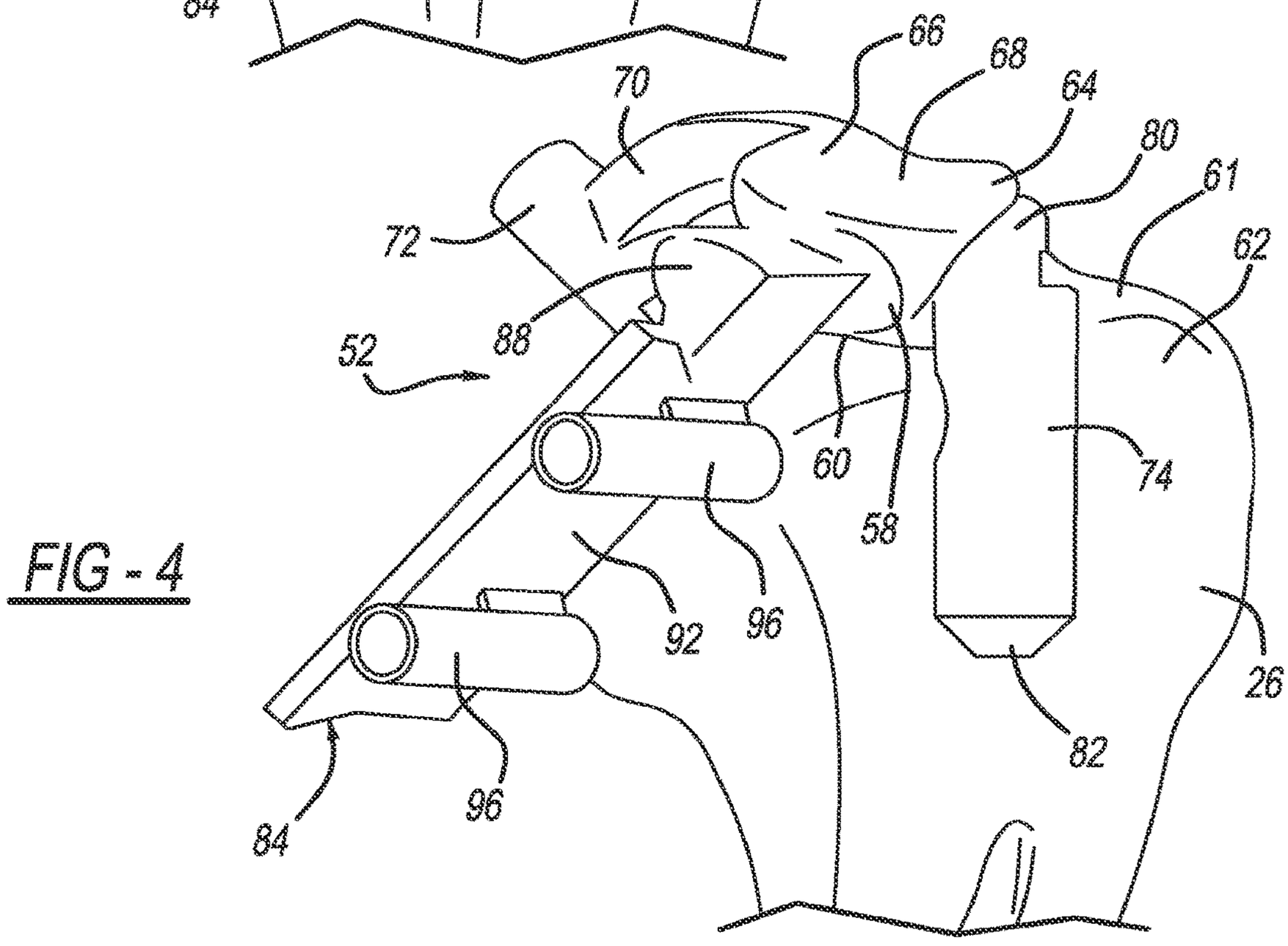
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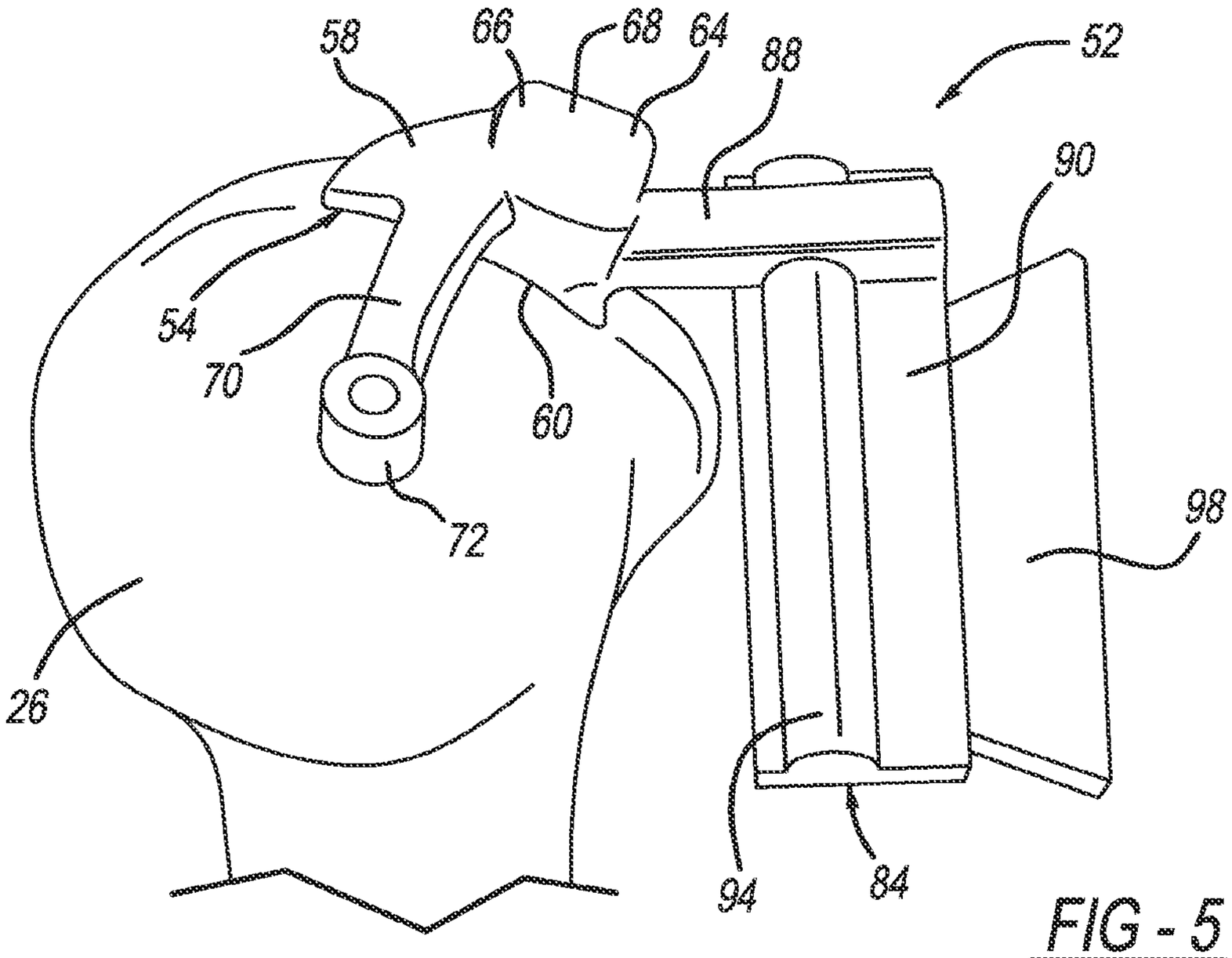
FIG - 4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64
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72
98
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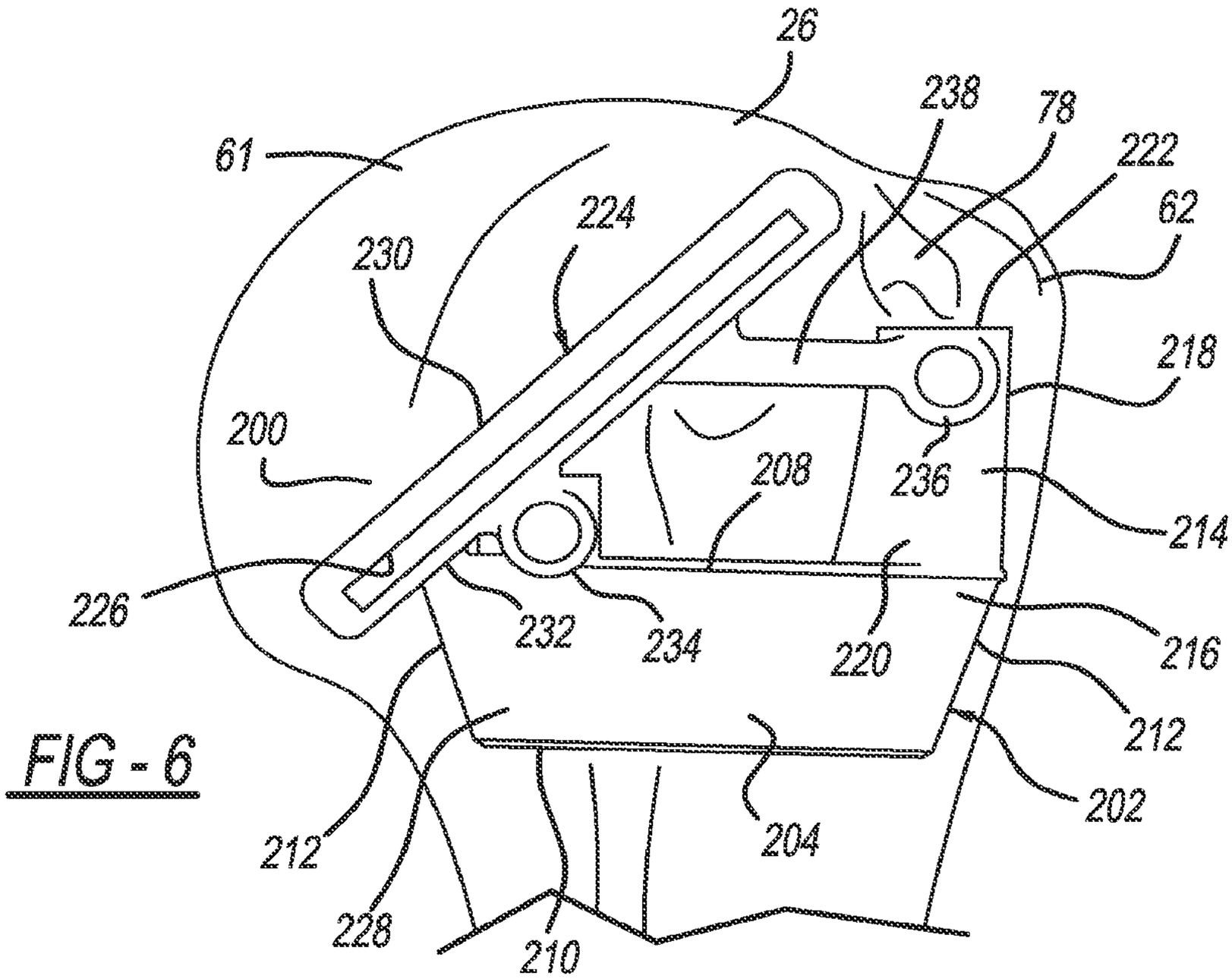
94
84

FIG - 5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78
222
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202
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FIG - 6

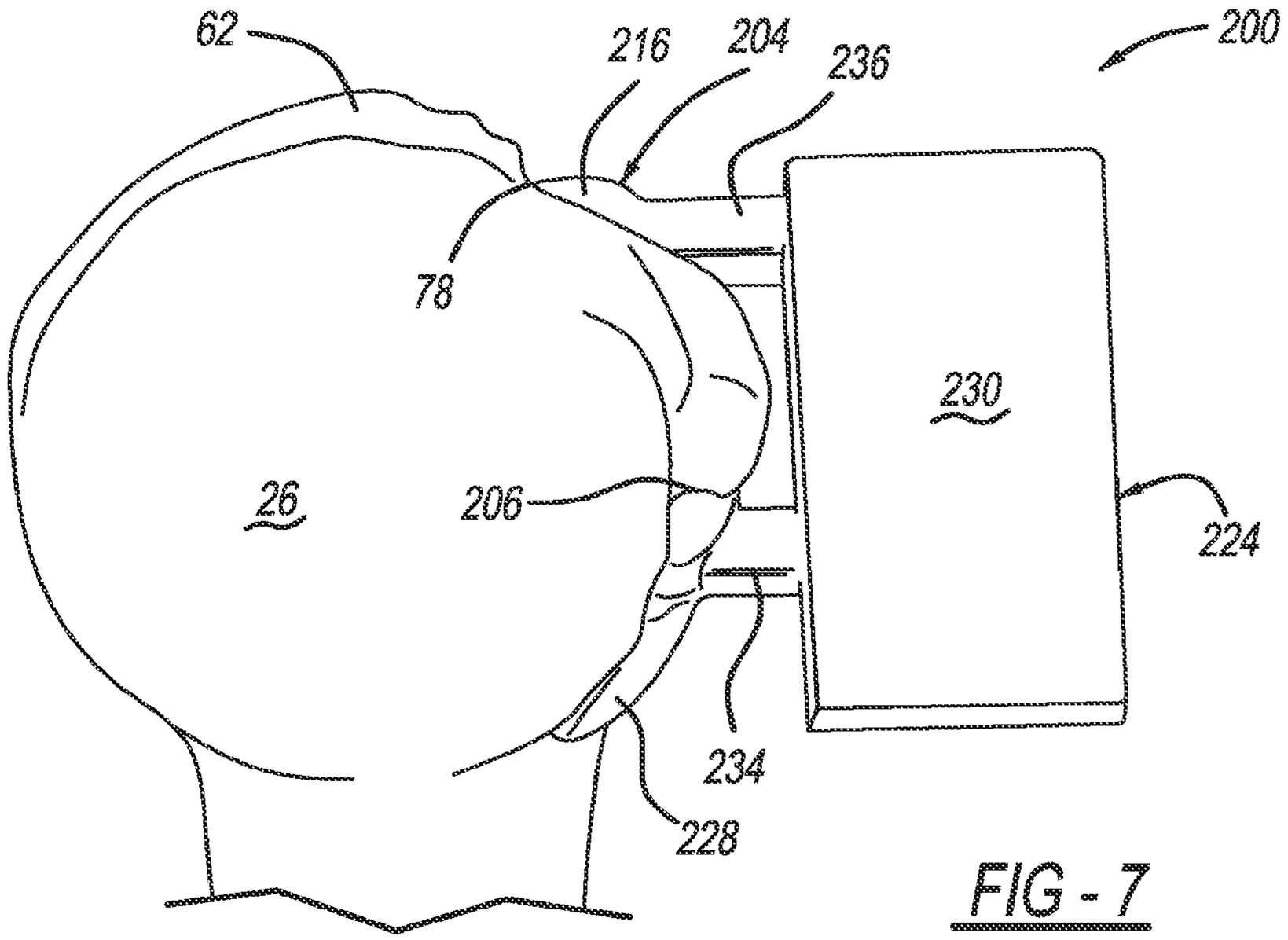
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FIG - 7

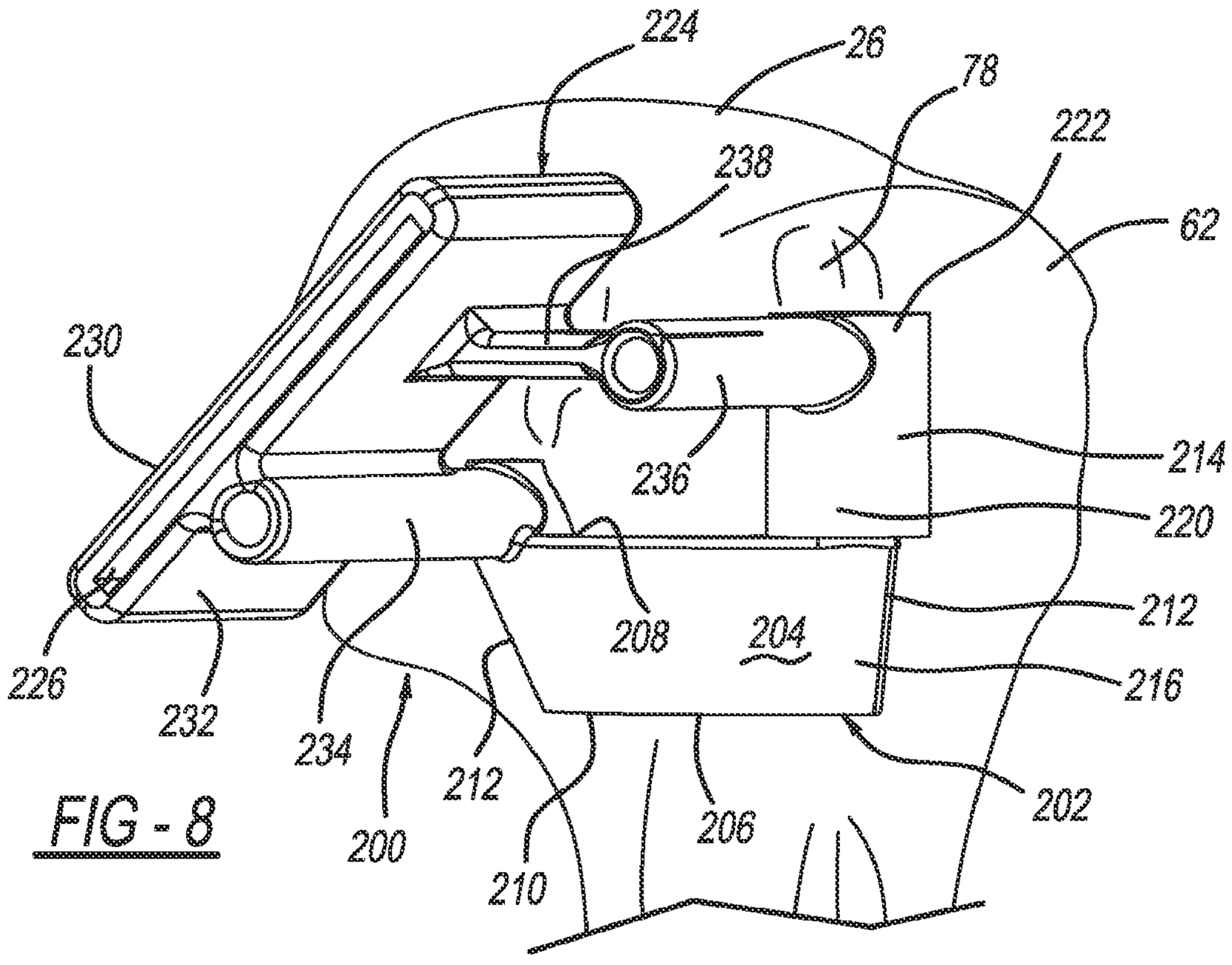
224
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FIG - 8

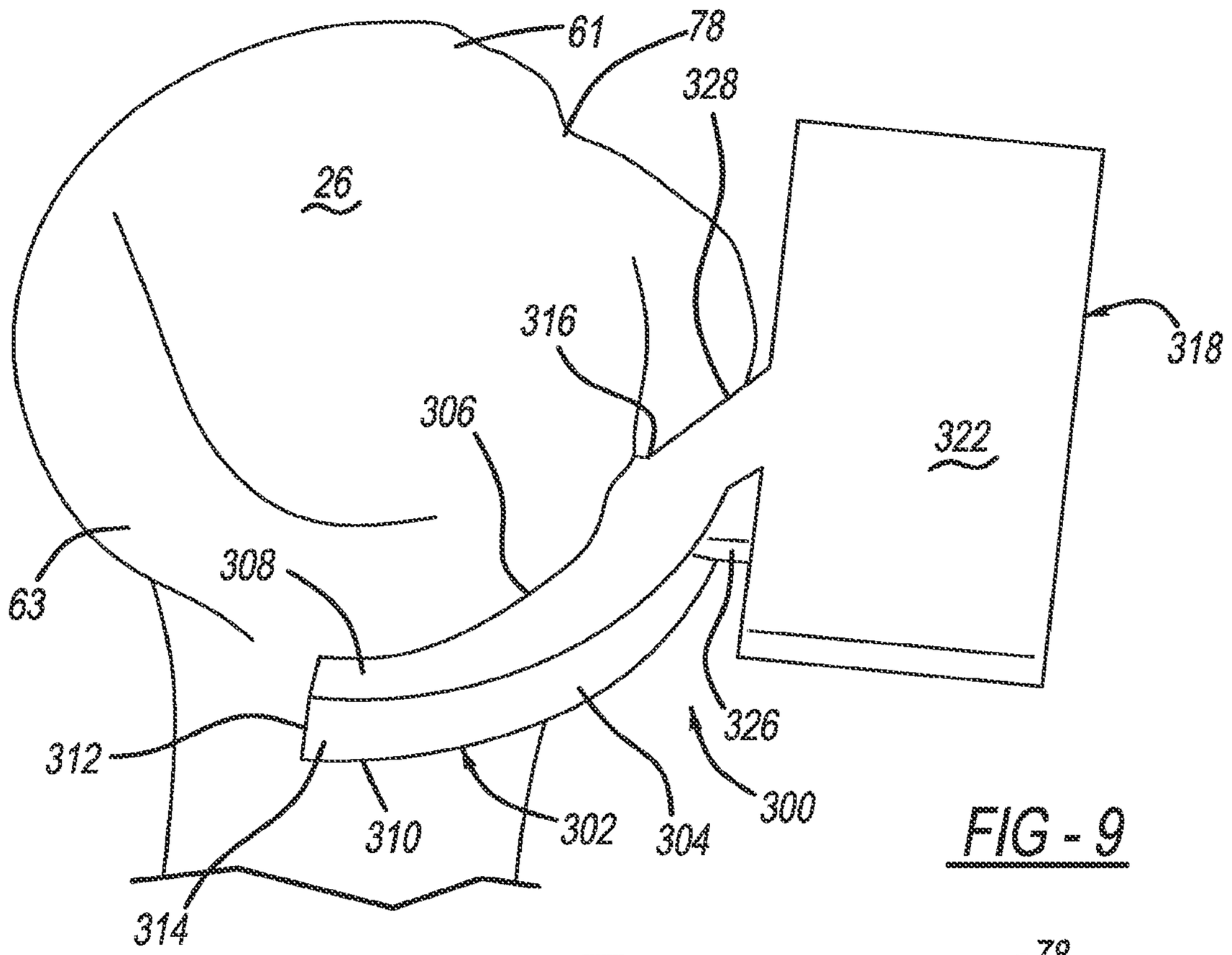
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FIG - 9

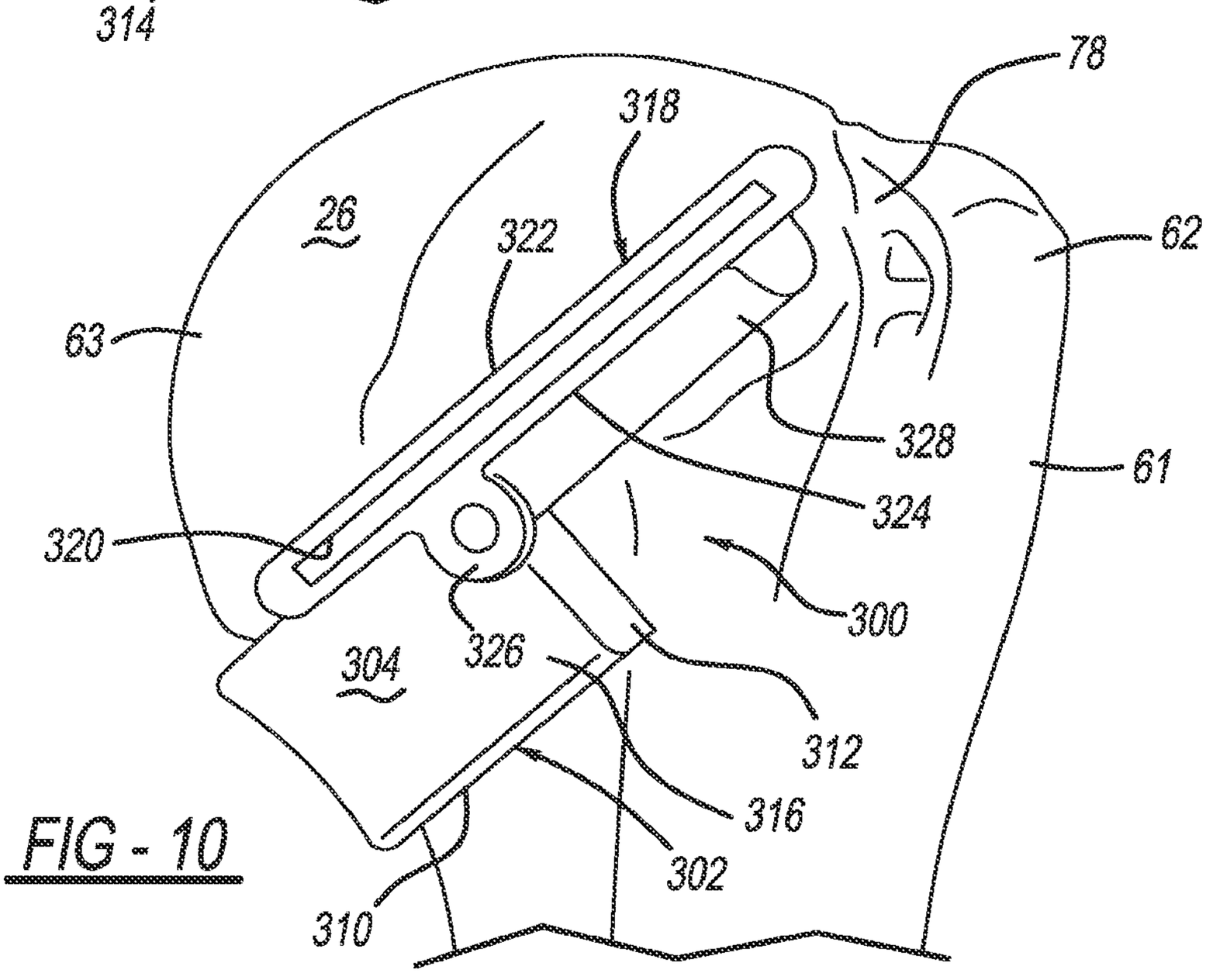
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FIG - 10

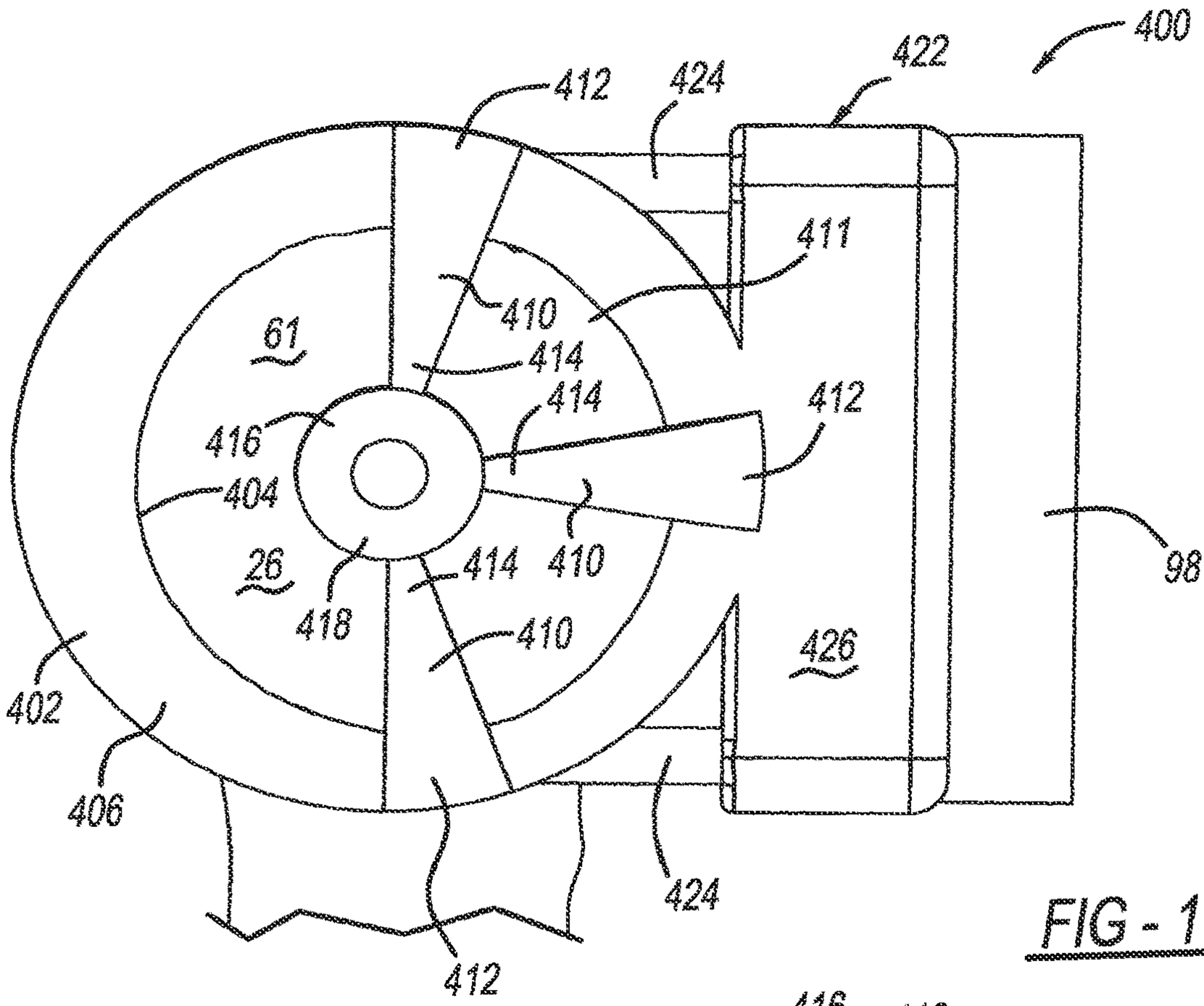
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FIG - 11

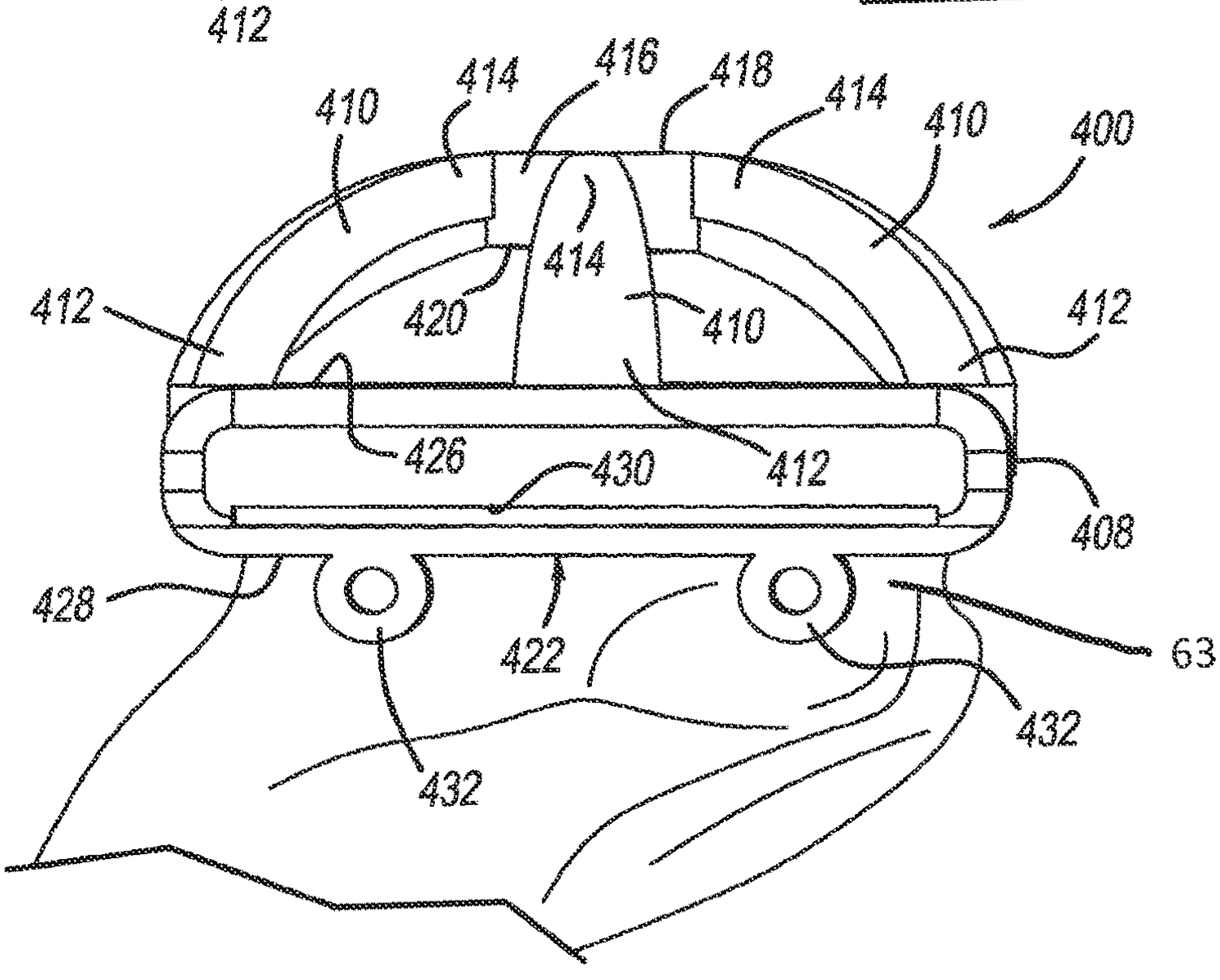
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FIG - 12

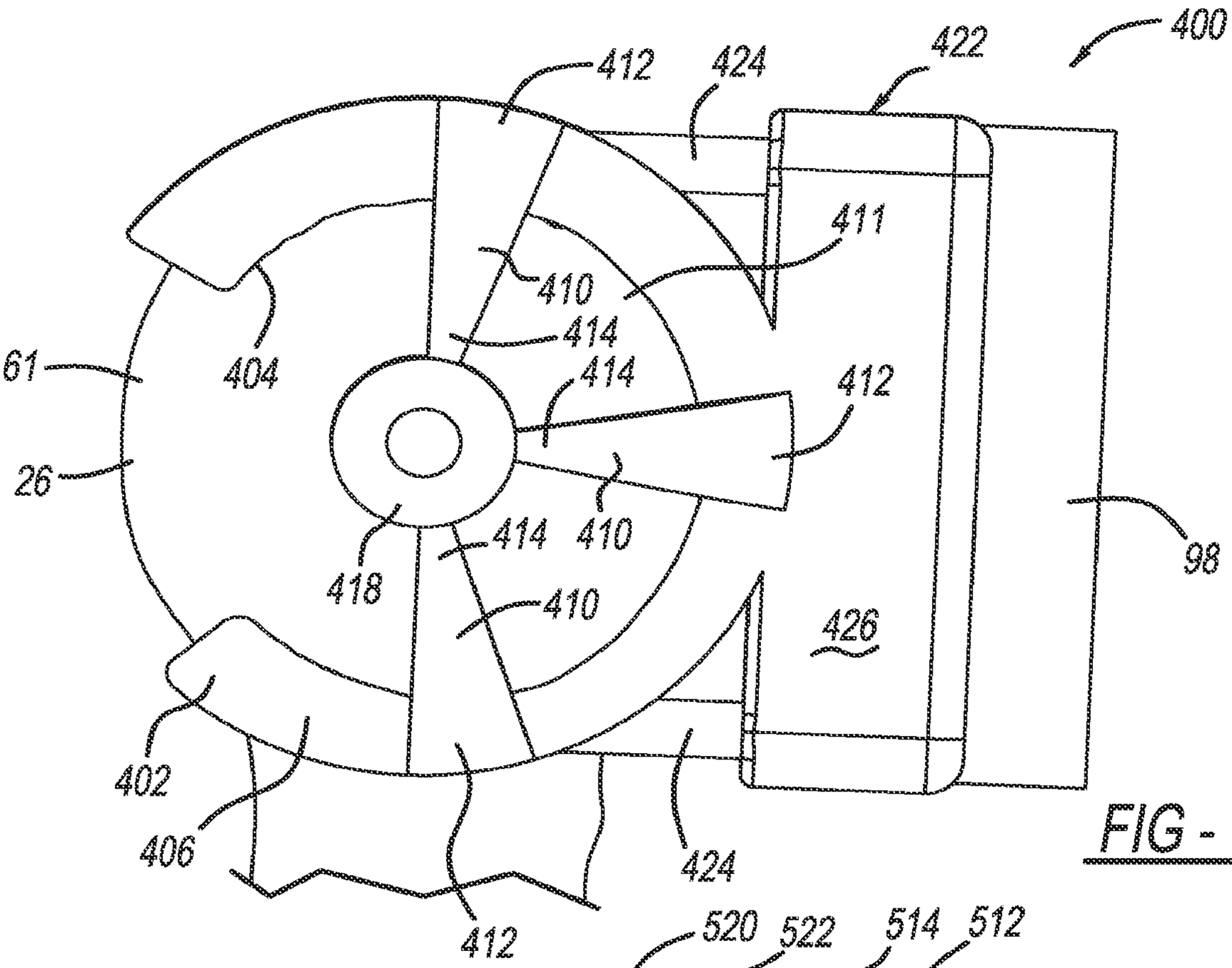
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FIG - 13

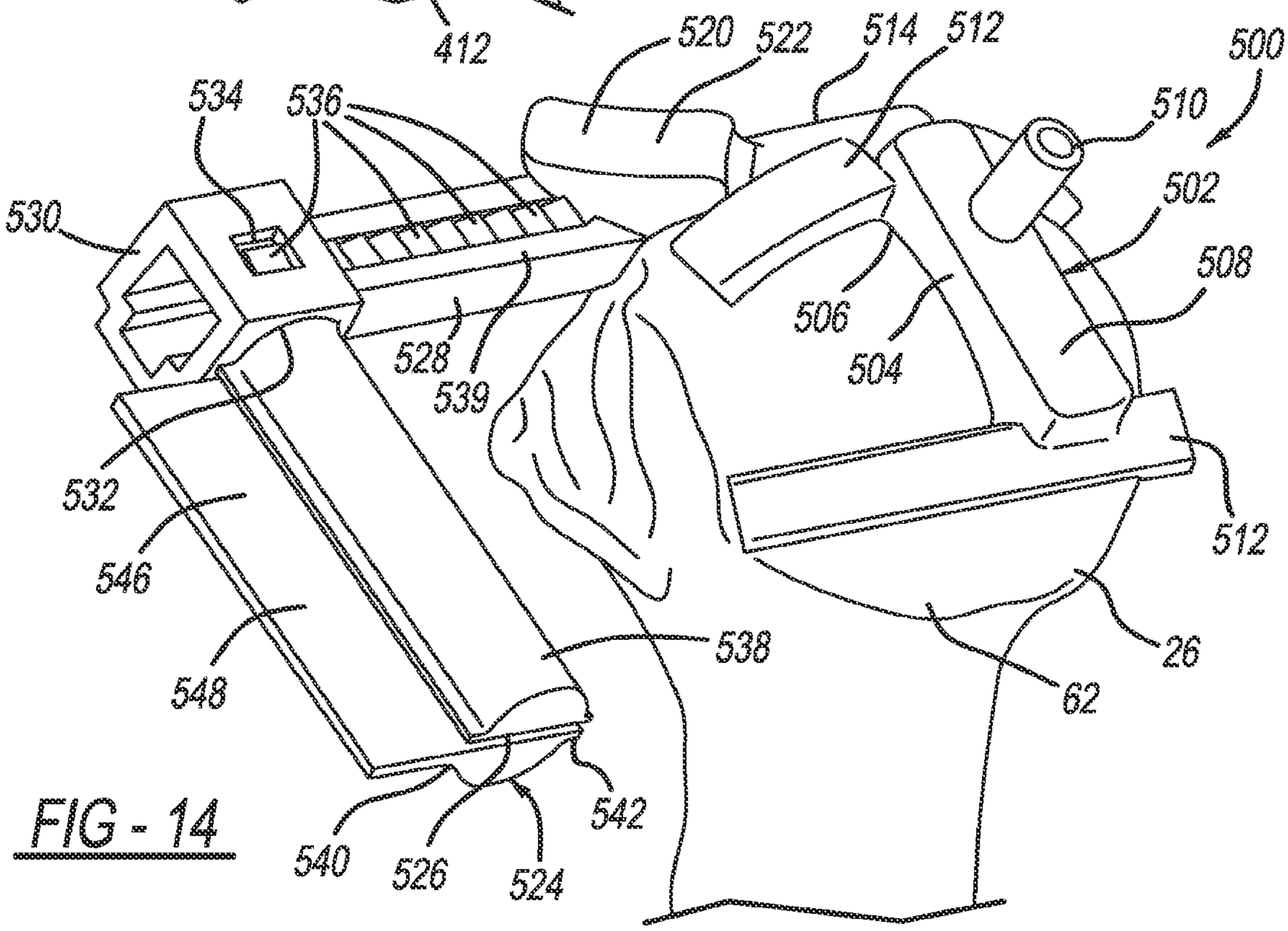
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FIG - 14

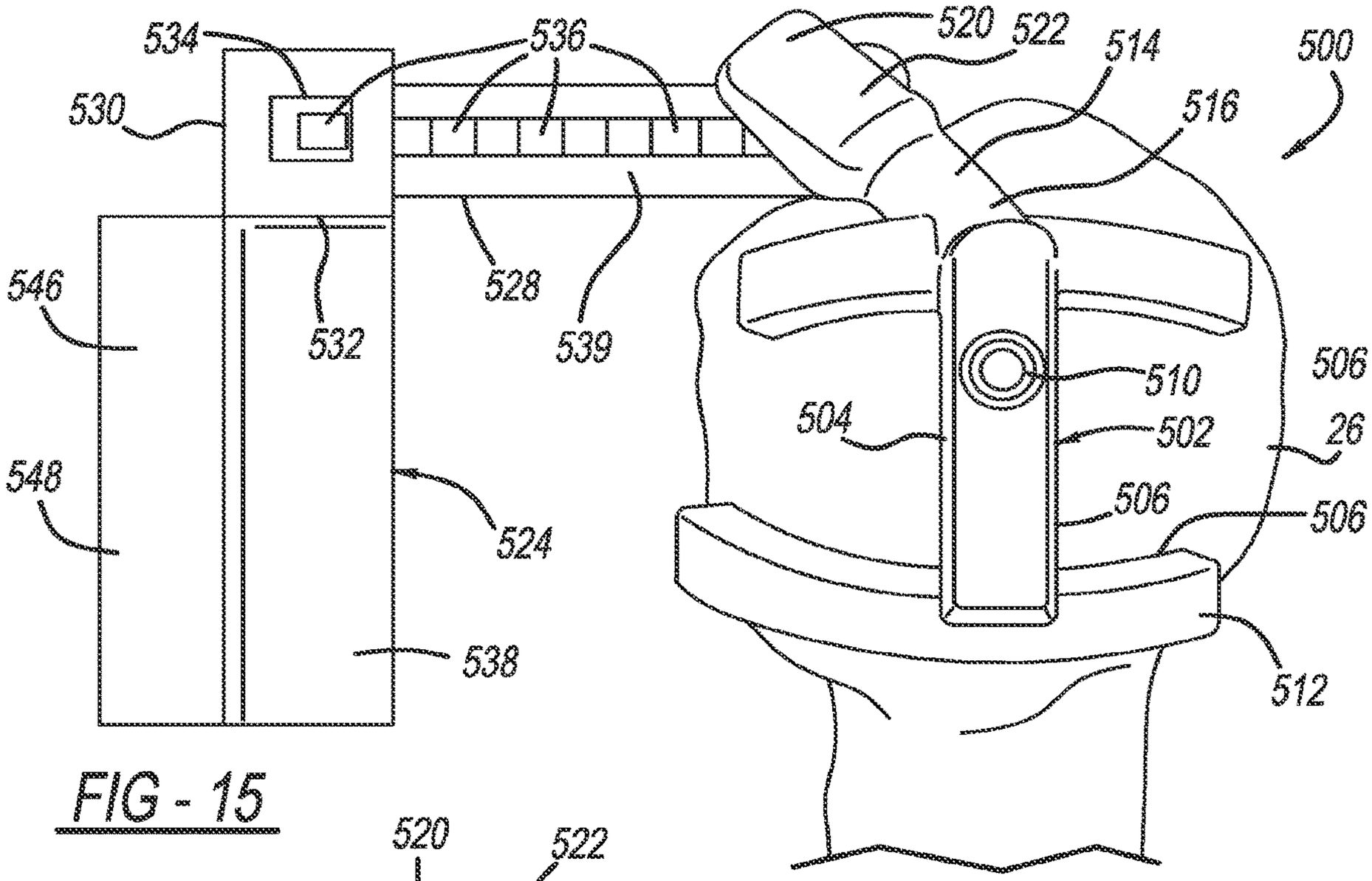
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FIG - 15

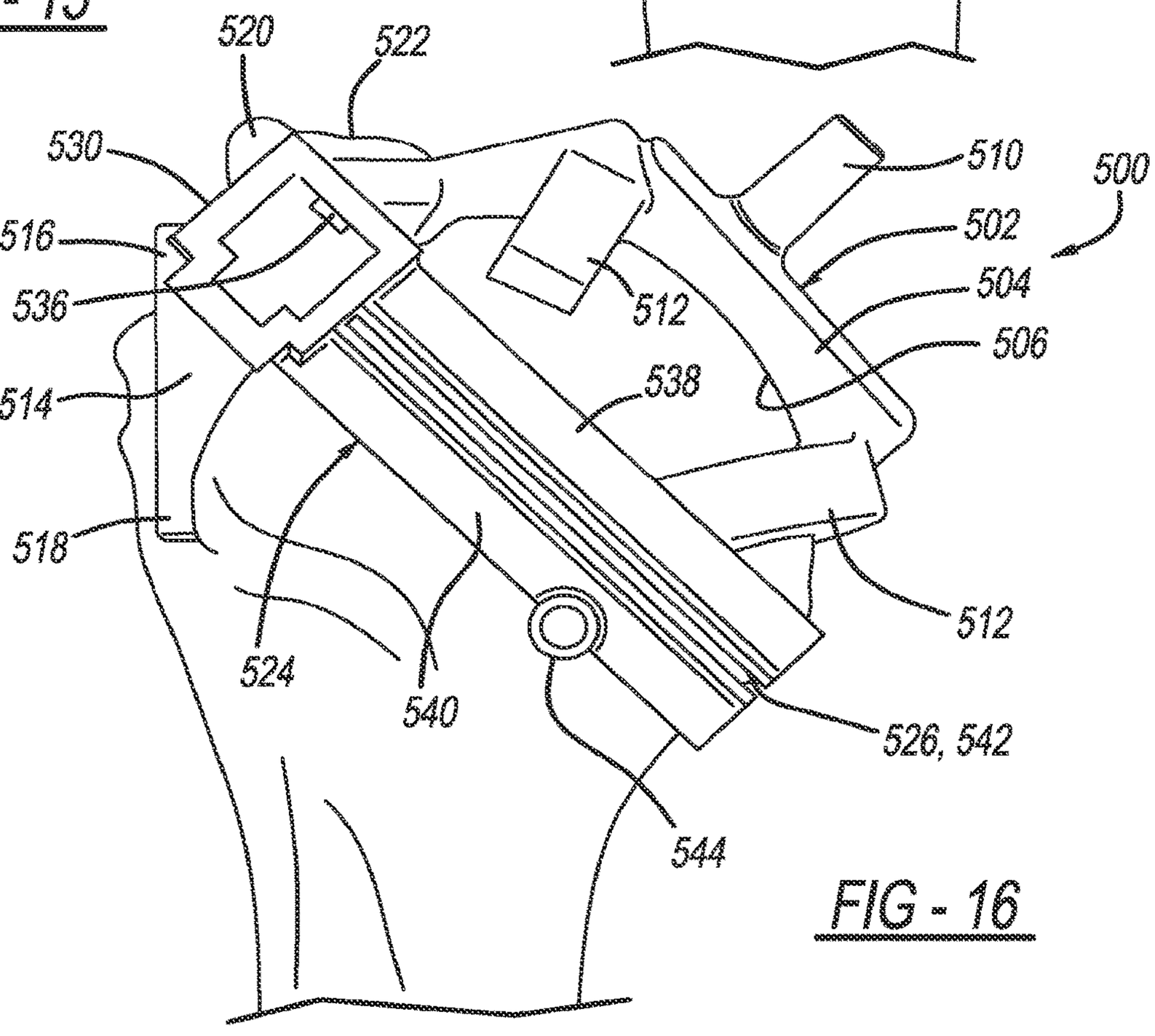
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FIG - 16

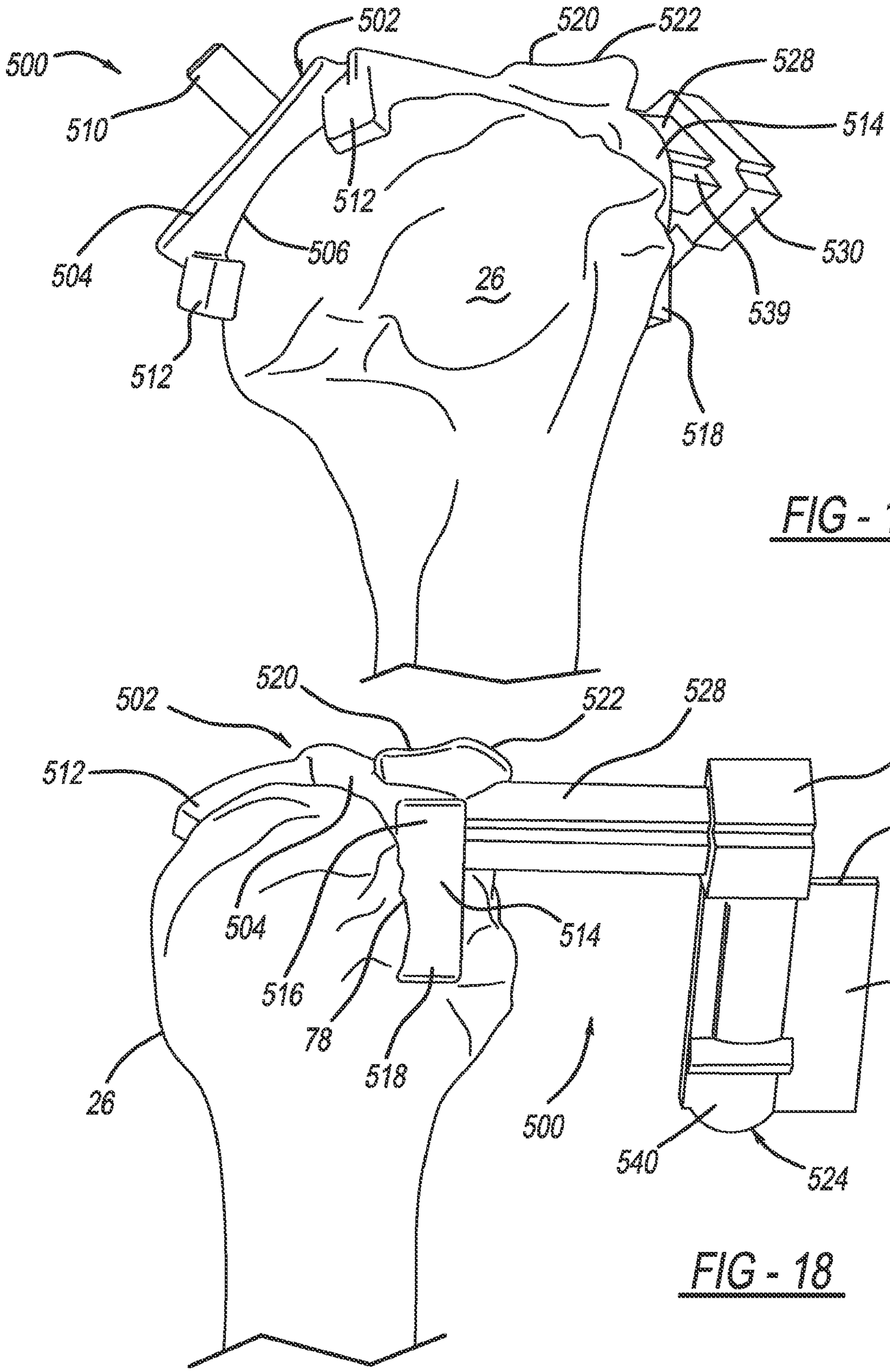
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FIG - 17

FIG - 18

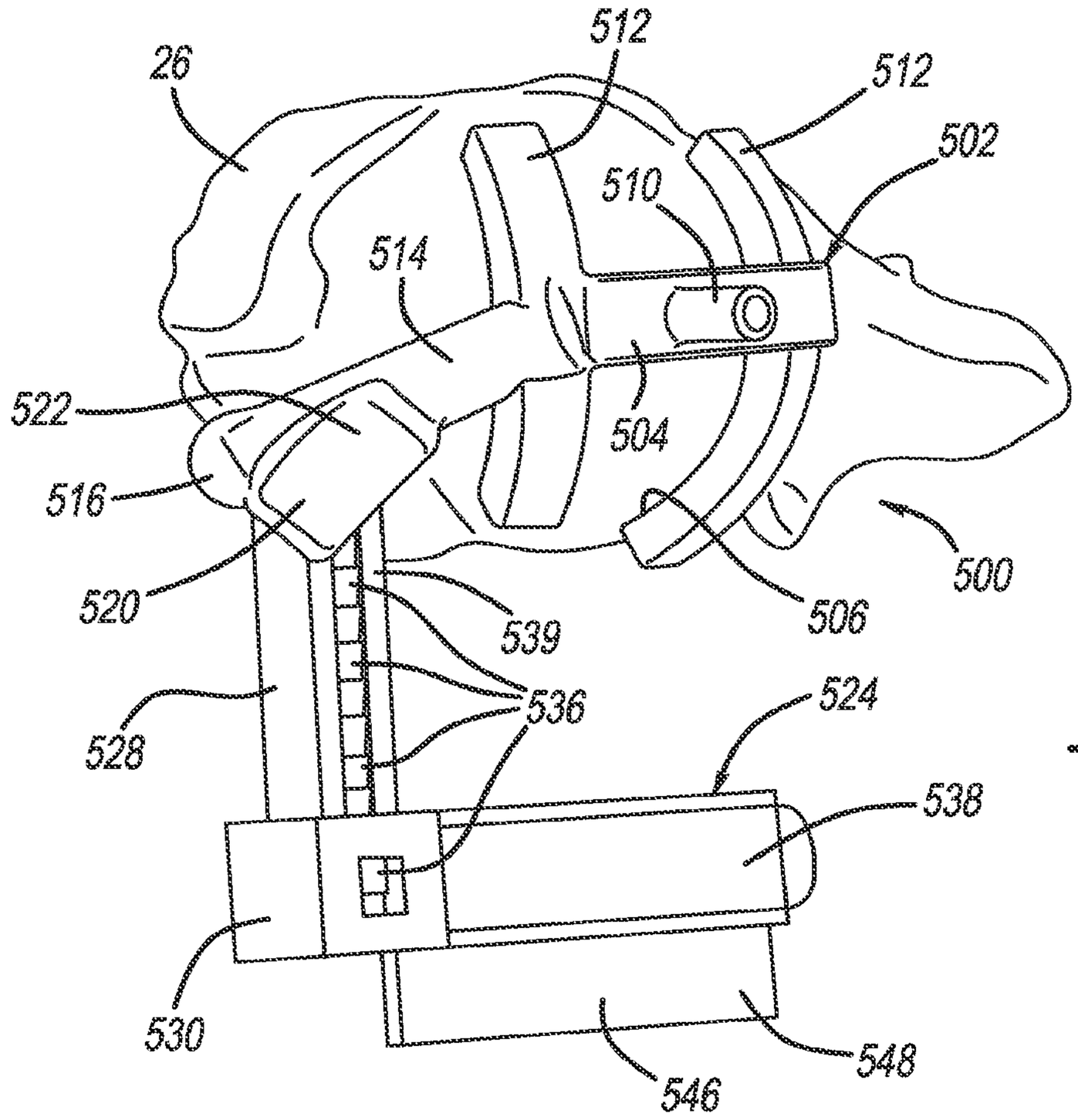
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FIG - 19

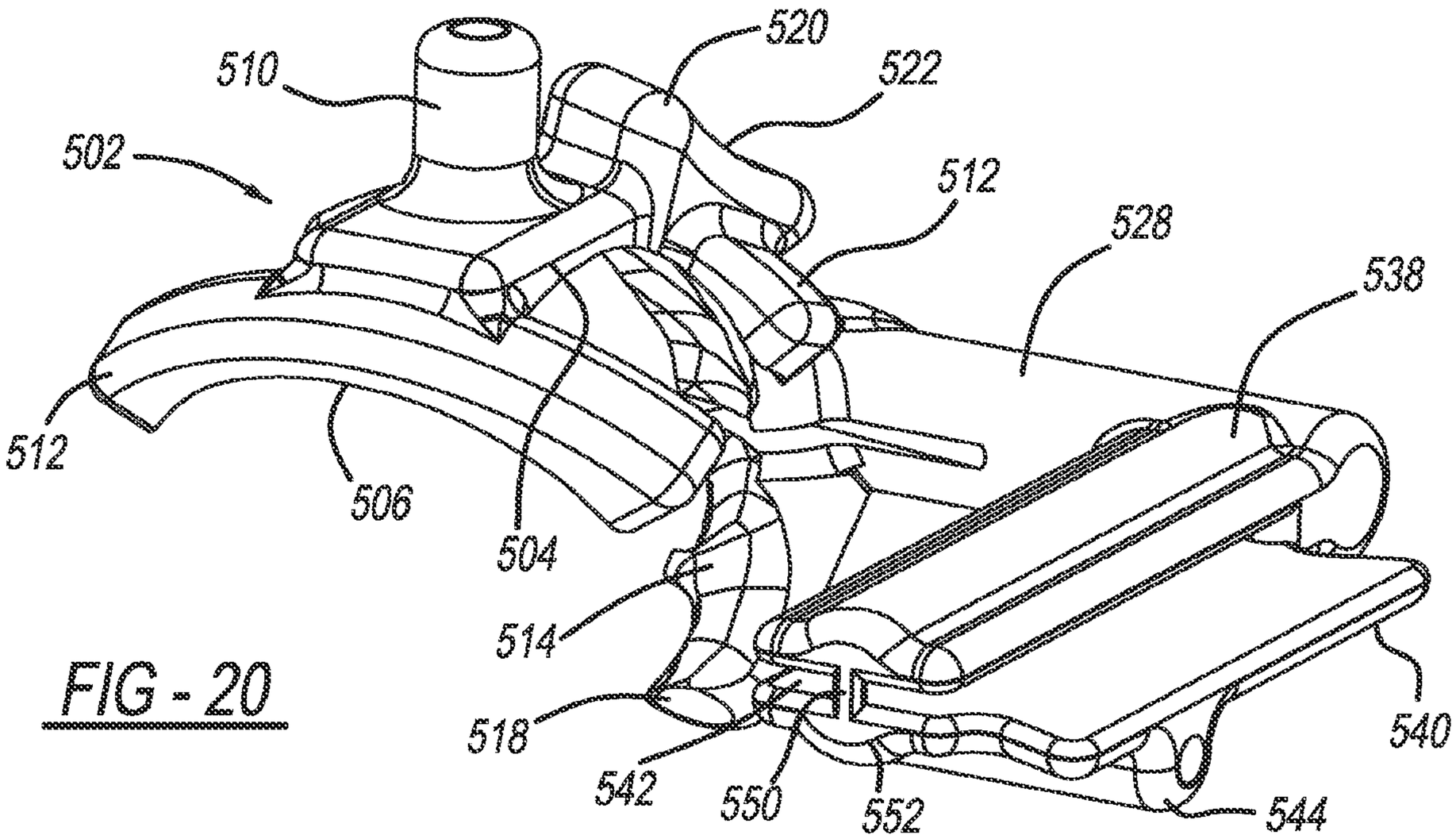
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FIG - 20

PATIENT-SPECIFIC HUMERAL GUIDE DESIGNS

FIELD

The present disclosure relates to humeral cut guide members.

BACKGROUND

This section provides background information related to the present disclosure which is not necessarily prior art.

During shoulder arthroplasty, the humeral bone may require resurfacing or resecting for receipt of a shoulder implant. Prior to surgery, it is common for the surgeon to take various images via X-ray, CT, ultrasound, MRI, or PET of the surgical area including the humeral bone. Based on these images, the surgeon can determine the best course of action for resurfacing or resecting the humeral bone, as well as determine whether the primary procedure for shoulder repair is an anatomical or reverse arthroplasty. During the surgery, however, it is not uncommon for the surgeon to determine that the preselected courses of action are not suitable for the patient. If the course of action changes during surgery, new instruments may be required to properly complete the resurfacing or resecting of the humeral bone before completing the arthroplasty procedure.

SUMMARY

This section provides a general summary of the disclosure, and is not a comprehensive disclosure of its full scope or all of its features.

The present disclosure provides a humeral cut guide member for resurfacing a humeral head. The humeral cut guide member includes a bone-engagement member including a first patient-specific bone-engagement surface that is complementary and made to substantially mate and nest in only one position on a specific patient's humeral head, and a registration member connected to the bone-engagement member including a second patient-specific bone engagement surface that is sized and made to substantially mate and nest in only one position with the specific patient's bicipital groove. The humeral cut guide member also includes a cut guide plate connected to the bone-engagement member and defining an elongated slot.

The present disclosure also provides a humeral cut guide member for resectioning or resurfacing a humeral head including a bone-engagement member including a first patient-specific bone-engagement surface that is complementary and made to substantially mate and nest in only one position on a specific patient's humeral head, and a registration member connected to the bone-engagement member including a second patient-specific bone engagement surface that is sized and made to substantially mate and nest in only one position with the specific patient's bicipital groove. The humeral cut guide member also includes a cut guide plate connected to the bone-engagement member and defining an elongated slot, wherein the cut guide plate is connected to the bone-engagement member by a tube-shaped member extending outward from the bone-engagement member, and the cut guide plate includes a connection portion for receipt of the tube-shaped member such that a position of the cut guide plate relative to the specific patient's humeral head is selectively adjustable along the tube-shaped member.

The present disclosure also provides a method of resectioning or resurfacing a humeral head using a humeral cut guide member including a bone-engagement member that includes a first patient-specific bone-engagement surface that is complementary and made to substantially mate and nest in only one position on a specific patient's humeral head, and including a cut guide plate connected to the bone-engagement member. The method includes affixing the humeral cut guide member to the only one position of the specific patient's humeral head; and selectively adjusting a position of the cut guide plate relative to the specific patient's humeral head by moving the cut guide plate along a tube-shaped member that extends from the bone-engagement member.

Further areas of applicability will become apparent from the description provided herein. The description and specific examples in this summary are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

DRAWINGS

The drawings described herein are for illustrative purposes only of selected embodiments and not all possible implementations, and are not intended to limit the scope of the present disclosure.

FIG. **1** is an exploded view of a prior art implant for reverse shoulder arthroplasty;

FIG. **2** is an environmental view of the prior art implant of FIG. **1**;

FIG. **3** is a perspective environmental view of a humeral cut guide member according to a first embodiment of the present disclosure;

FIG. **4** is another perspective environmental view of the humeral cut guide member according to the first embodiment of the present disclosure;

FIG. **5** is another perspective environmental view of the humeral cut guide member according to the first embodiment of the present disclosure;

FIG. **6** is a perspective environmental view of a humeral cut guide member according to a second embodiment of the present disclosure;

FIG. **7** is another perspective environmental view of the humeral cut guide member according to the second embodiment of the present disclosure;

FIG. **8** is another perspective environmental view of the humeral cut guide member according to the second embodiment of the present disclosure;

FIG. **9** is a perspective environmental view of a humeral cut guide member according to a third embodiment of the present disclosure;

FIG. **10** is another perspective environmental view of the humeral cut guide member according to the third embodiment of the present disclosure;

FIG. **11** is a perspective environmental view of a humeral cut guide member according to a fourth embodiment of the present disclosure;

FIG. **12** is another perspective environmental view of the humeral cut guide member according to the fourth embodiment of the present disclosure;

FIG. **13** is another perspective environmental view of a modified humeral cut guide member according to the fourth embodiment of the present disclosure;

FIG. **14** is a perspective environmental view of a humeral cut guide member according to a fifth embodiment of the present disclosure;

FIG. **15** is another perspective environmental view of the humeral cut guide member according to the fifth embodiment of the present disclosure;

FIG. **16** is another perspective environmental view of the humeral cut guide member according to the fifth embodiment of the present disclosure;

FIG. **17** is another perspective environmental view of the humeral cut guide member according to the fifth embodiment of the present disclosure;

FIG. **18** is another perspective environmental view of the humeral cut guide member according to the fifth embodiment of the present disclosure;

FIG. **19** is another perspective environmental view of the humeral cut guide member according to the fifth embodiment of the present disclosure; and

FIG. **20** is a perspective view of a modified humeral cut guide member according to the fifth embodiment of the present disclosure.

Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION

Example embodiments will now be described more fully with reference to the accompanying drawings.

The present disclosure generally provide patient-specific surgical instruments that include, for example, alignment guides, drill guides, and other tools for use in shoulder joint replacement, shoulder resurfacing procedures and other procedures related to the shoulder joint or the various bones of the shoulder joint, including the humeral head. The present disclosure can be applied to anatomic shoulder replacement and reverse shoulder replacement. The patient-specific instruments can be used either with conventional implant components or with patient-specific implant components and/or bone grafts that are prepared using computer-assisted image methods according to the present disclosure. Computer modeling for obtaining three-dimensional images of the patient's anatomy using medical scans of the patient's anatomy (such as MRI, CT, ultrasound, X-rays, PET, etc.), the patient-specific prosthesis components and the patient-specific guides, templates and other instruments, can be prepared using various commercially available CAD programs and/or software available, for example, by Object Research Systems or ORS, Montreal, Canada.

The patient-specific instruments and any associated patient-specific implants and bone grafts can be generally designed and manufactured based on computer modeling of the patient's 3-D anatomic image generated from medical image scans including, for example, X-rays, MRI, CT, PET, ultrasound or other medical scans. The patient-specific instruments can have a three-dimensional engagement surface that is complementary and made to substantially mate and match in only one position (i.e., as a substantially negative or mirror or inverse surface) with a three-dimensional bone surface with or without associated soft tissues, which is reconstructed as a 3-D image via the aforementioned CAD or software. Very small irregularities need not be incorporated in the three-dimensional engagement surface. The patient-specific instruments can include custom-made guiding formations, such as, for example, guiding bores or cannulated guiding posts or cannulated guiding extensions or receptacles that can be used for supporting or guiding other instruments, such as drill guides, reamers, cutters, cutting guides and cutting blocks or for inserting guiding pins, K-wire, or other fasteners according to a surgeon-approved pre-operative plan.

In various embodiments, the patient-specific instruments of the present disclosure can also include one or more patient-specific guide members for receiving and guiding a tool, such as a drill or saw at corresponding patient-specific insertion points and orientations relative to a selected anatomic or reverse axis for the specific patient. The patient-specific instruments can include guiding or orientation formations and features for guiding the implantation of patient-specific or off-the-shelf implants associated with the surgical procedure. The geometry, shape and orientation of the various features of the patient-specific instruments, as well as various patient-specific implants and bone grafts, if used, can be determined during the pre-operative planning stage of the procedure in connection with the computer-assisted modeling of the patient's anatomy. During the pre-operative planning stage, patient-specific instruments, custom, semi-custom or non-custom implants and other non-custom tools, can be selected and the patient-specific components can be manufactured for a specific-patient with input from a surgeon or other professional associated with the surgical procedure.

In the following discussion, the terms "patient-specific", "custom-made" or "customized" are defined to apply to components, including tools, implants, portions or combinations thereof, which include certain geometric features, including surfaces, curves, or other lines, and which are made to closely conform substantially as mirror-images or negatives or complementary surfaces of corresponding geometric features or anatomic landmarks of a patient's anatomy obtained or gathered during a pre-operative planning stage based on 3-D computer images of the corresponding anatomy reconstructed from image scans of the patient by computer imaging methods. Further, patient-specific guiding features, such as, guiding apertures, guiding slots, guiding members or other holes or openings that are included in alignment guides, drill guides, cutting guides, rasps or other instruments or in implants are defined as features that are made to have positions, orientations, dimensions, shapes and/or define cutting planes and axes specific to the particular patient's anatomy including various anatomic or mechanical axes based on the computer-assisted pre-operative plan associated with the patient.

The patient-specific guide members can be configured to mate in alignment with natural anatomic landmarks by orienting and placing the corresponding alignment guide intra-operatively on top of the bone to mate with corresponding landmarks. The anatomic landmarks function as passive fiducial identifiers or fiducial markers for positioning of the various alignment guide members, drill guides or other patient-specific instruments.

The various patient-specific alignment guide members can be made of any biocompatible material, including, polymer, ceramic, metal or combinations thereof. The patient-specific alignment guide members can be disposable and can be combined or used with reusable and non-patient-specific cutting and guiding components.

More specifically, the present disclosure provides various embodiments of patient-specific humeral cut guide members for anatomic and reverse arthroplasty. The humeral cut guides of the present disclosure can have patient-specific engagement surfaces that reference various portions of the shoulder joint and include tubular drill guides, guiding bores or sleeves or other guiding formations that can accurately position guide pins for later humeral preparation and implantation procedures and for alignment purposes, including implant position control, implant version control, implant inclination control for both anatomic and reverse arthroplasty.

In the following, when a portion of a humeral guide member is described as "referencing" a portion of the

anatomy, it will be understood that the referencing portion of the humeral guide member is a patient-specific portion that mirrors or is a negative of the corresponding referenced anatomic portion.

In some embodiments the humeral guide member can have built-in holes, openings or windows that allow the surgeon to mark the humeral bone or a model of the humeral bone with a marking pen, burr, scalpel, or any other device that can create markings to be used as landmarks on or in the humeral bone or humeral model. These landmarks can be used for the orientation of a secondary guide.

Referring to FIGS. **1** and **2**, a prior art reverse shoulder implant **10** is illustrated. The reverse shoulder implant **10** includes a humeral stem **12**, a humeral tray **14**, a humeral bearing **16**, a glenosphere **18** and a baseplate **20** having a plate portion **22** and a central boss **24**. The humeral stem **12** is implanted in the humeral bone **26** and has a proximal end **28** coupled via a Morse taper connection to a male taper **30** extending from a plate **32** of the humeral tray **14**. The glenosphere **18** can be modular and include a head **34** articulating with the bearing **16** and an offset double-taper component **36**. The double-taper component **36** has a first tapered portion **38** coupled to a corresponding tapered opening **40** of the head **34** and a second tapered portion **42** coupled to the central boss **24** of the glenoid baseplate **20**. A central screw **44** passes through the baseplate **20** into the glenoid face **46** of the patient's scapula. Peripheral screws **48** are used to lock the baseplate **20** in the glenoid face **46**.

As best illustrated in FIG. **2**, humeral bone **26** includes a planar surface **50** for abutment with plate **32** of humeral tray **14**. To provide planar surface **50**, humeral bone **26** is cut using a tool such as a bone saw (not shown). To properly orient the saw at the correct angle relative to humeral bone **26**, the present disclosure provides a humeral cut guide system **52**.

Referring to FIGS. **3-5**, an exemplary humeral cut guide system **52** according to an aspect of the present disclosure is illustrated. Humeral cut guide system **52** includes a patient-specific humeral cut guide member **54**. Humeral cut guide member **54** is configured to be patient-specific such that humeral cut guide member **54** mates with and nests in only one position on humeral bone **26**. In this regard, humeral cut guide member **54** includes a bone-engagement member **58** having a bone-engagement surface **60** that is complementary and made to substantially mate and nest in only one position (i.e., as a substantially negative or mirror or inverse surface) with a three-dimensional bone surface **61** of humeral bone **26** with or without associated soft tissues, which is reconstructed as a 3-D image via the aforementioned CAD or software.

As best illustrated in FIG. **3**, bone-engagement member **58** and bone-engagement surface **60** are each pie-shaped and specifically designed to mate and nest on a proximal portion of the lesser tuberosity **62** of humeral bone **26**. An opposing surface **64** of bone-engagement member **58** defines a protrusion **66** that provides a curved contact surface **68** that allows humeral cut guide member **54** to be manipulated by the surgeon into correct alignment on the humeral bone **26**. In other words, the surgeon may place a finger-tip upon contact surface **68**, which allows the surgeon to more easily orient the humeral cut guide member **54** in a manner that bone-engagement surface **60** properly aligns with bone surface **62** of humeral bone **26**.

A curved connecting member **70** extends away from bone-engagement member **58** and connects bone-engagement member **58** with a patient-specific pin guide aperture **72**. Pin guide aperture **72** is aligned per the specific patient and allows for passage of a drill, Steinmann pin, or guidewire (not shown), that allows humeral bone **26** to be reamed at the appropriate location for any desired resurfacing of humeral bone **26**. As illustrated, connecting member **70** is spaced apart from humeral bone **26**. It should be understood, however, that connecting member **70** may be designed to abut humeral bone **26**. In such a case, connecting member **70** may also include a patient-specific mating surface that is designed to mate and nest with humeral bone **26** in a single position.

A registration member **74** extends away from bone-engagement member **58** in a direction different from that of connecting member **70**. Similar to bone-engagement member **58**, registration member **74** includes a bone-engagement surface **76** that is designed to mate and nest with humeral bone **26** in a single position. Specifically, bone-engagement surface **76** of registration member **74** is patient-specifically sized and shaped to mate with the bicipital groove **78** (see, e.g., FIG. **6**) of humeral bone **26**. Thus, registration member **74** is an elongated tab-shaped member having a proximal end **80** unitary or connected to bone-engagement member **58** and a distal end **82** located away from bone-engagement member **58**. With the pie-shaped bone-engagement member **58** and elongated registration member **74**, humeral cut guide member **54** is configured to nest with humeral head **26** in a single position with as little material as possible. In this manner, a majority (i.e., at least 75%) of humeral head **26** is exposed during the surgical procedure to allow the surgeon greater visual access to the humeral head **26**.

Humeral cut guide member **54** includes a cut guide plate **84** including an elongated slot **86**. As best shown in FIG. **5**, cut guide plate **84** is unitary or connected to bone-engagement member **58** with a cylindrically-shaped member **88** that extends outward from bone-engagement member **58** in a direction different from each of connecting member **70** and registration member **74**. Cylindrically-shaped member **88** extends outward from bone-engagement member **88** to an extent that cut guide plate **84** will be spaced apart from humeral head **26**. By spacing cut guide plate **84** away from humeral head **26**, the unnecessary removal of soft-tissue (e.g., muscle, cartilage, etc.) from humeral head **26** is prevented, which assists in the patient's recovery after the arthroplasty. It should be understood, however, that cut guide plate **84** may be configured to abut humeral bone **26** during pre-operative design of humeral cut guide system **52**, if desired.

Cut guide plate **84** includes an upper surface **90** and a lower surface **92**, with elongated slot **86** positioned therebetween. Upper surface **90** includes a reinforcing rib **94** extending along an entire length of upper surface **90**. Lower surface **92** defines a pair of tube-shaped apertures **96**. Tube-shaped apertures are configured to receive a drill (not shown) for drilling humeral bone **26**. After drilling of the humeral bone **26**, a pair of pins (not shown) such as Steinmann pins or K-wires may be implanted in humeral bone **26**, which may be used to assist in securing humeral cut guide member **54** to humeral bone **26**. Alternatively, the pair of pins may be used to support a secondary cut guide (not shown) that is configured to assist in resecting or resurfacing of the humeral bone **26** at a different angle in comparison to the angle defined by humeral cut guide member **54**. An exemplary secondary cut guide may be found in U.S. Ser. No. 14/265,577 assigned to Biomet Manufacturing, LLC. In this regard, after implantation of the pins, the humeral cut guide member **54** may be removed from humeral bone **26**

with the pins remaining in place. The secondary cut guide may then be mated with the pins relative to the humeral bone **26**.

Although not required, lower surface **92** may extend outward relative to upper surface **90** such that a shelf or platform **98** is formed. Platform **98** allows for a greater amount of surface area for the tool blade (not shown) to lie upon during resurfacing or resecting of the humeral bone **26**. In this manner, the tool blade is substantially prevented from being improperly angled during the resurfacing or resecting of the humeral bone **26** to form planar surface **50**. It should be understood that if platform **98** is used, upper surface **90** and reinforcing rib **94** may be omitted. In such a configuration, the tool blade would simply lie upon platform **98** during resurfacing or resecting of the humeral bone **26**.

Now referring to FIGS. **6-8**, another exemplary humeral cut guide system **200** is illustrated. Humeral cut guide system **200** includes a humeral cut guide member **202**. Humeral cut guide member **202** is configured to be patient-specific such that humeral cut guide member **202** mates with and nests in only one position on humeral bone **26**. In this regard, humeral cut guide member **202** includes a bone-engagement member **204** having a bone-engagement surface **206** that is complementary and made to substantially mate and nest in only one position (i.e., as a substantially negative or mirror or inverse surface) with a three-dimensional bone surface **61** of humeral bone **26** with or without associated soft tissues, which is reconstructed as a 3-D image via the aforementioned CAD or software.

As best illustrated in FIG. **6**, bone-engagement member **204** and bone-engagement surface **206** are specifically designed to mate and nest on a distal portion of the lesser tuberosity **62** of humeral bone **26**. In this regard, a bone-engagement member **204** is a curved member including an upper edge **208** located adjacent the distal portion of the less tuberosity **62**, an opposing lower edge **210**, and side edges **212**.

As best illustrated in, for example, FIGS. **7** and **8**, bone-engagement member **204** wraps about a portion of humeral bone **26** in the medial direction from the bicipital groove **78**. A registration member **214** is located at a first end **216** of bone-engagement member **204**. Registration member **214** extends away from upper edge **208** of bone-engagement member **204** in a direction substantially orthogonal to bone-engagement member **204**. Similar to bone-engagement member **204**, registration member **214** includes a bone-engagement surface **218** that is designed to mate and nest with humeral bone **26** in a single position.

Specifically, bone-engagement surface **218** of registration member **214** is patient-specifically sized and shaped to mate with the bicipital groove **78** of humeral bone **26**. Thus, registration member **214** is an elongated tab-shaped member having a proximal end **220** unitary or connected to bone-engagement member **214** and a distal end **222** located away from upper edge **208**. With the bone-engagement member **204** and elongated registration member **214**, humeral cut guide member **204** is configured to nest with humeral head **26** at a position that allows for nearly an entirety (i.e., at least 90%) of humeral head **26** to be exposed during the surgical procedure to allow the surgeon greater visual access to the humeral head **26**.

Humeral cut guide member **202** includes a cut guide plate **224** including an elongated slot **226**. As best shown in FIG. **8**, cut guide plate **224** is unitary or connected to bone-engagement member **214** at a second end **228** of bone-engagement member **214**. Specifically, cut guide plate **224** includes an upper surface **230** and a lower surface **232**, with elongated slot **226** positioned therebetween. Lower surface **232** defines a first tube-shaped aperture **234** that, in addition to being configured to receive a drill (not shown) for drilling humeral bone **26**, connects cut guide plate **224** to second end **228**. A second tube-shaped aperture **236** is located at distal end **222** of registration member **214**, and is connected to cut guide plate **224** via a connecting arm **238**.

Similar to the above-described embodiment illustrated in FIGS. **3-5**, after drilling of the humeral bone **26**, a pair of pins (not shown) such as Steinmann pins or K-wires may be implanted in humeral bone **26** using first and second tube-shaped apertures **234** and **236**, which may be used to assist in securing humeral cut guide member **202** to humeral bone **26**. Alternatively and as also described in the exemplary embodiment illustrated in FIGS. **3-5**, the pair of pins may be used to support a secondary cut guide (not shown) that is configured to assist in resecting or resurfacing of the humeral bone **26** at a different angle in comparison to the angle defined by humeral cut guide member **202**.

Although cut guide plate **224** is illustrated as being spaced apart from humeral head **26**, it should be understood that cut guide plate **224** may be configured to abut humeral bone **26** during pre-operative design of humeral cut guide system **52**, if desired. By spacing cut guide plate **224** away from humeral head **26**, however, the unnecessary removal of soft-tissue (e.g., muscle, cartilage, etc.) from humeral head **26** is prevented, which assists in the patient's recovery after the arthroplasty. Further, although not required, lower surface **232** may extend outward relative to upper surface **230** such that a shelf or platform **98** (see FIG. **5**, described above) is formed. Platform **98** allows for a greater amount of surface area for the tool blade (not shown) to lie upon during resurfacing or resecting of the humeral bone **26**. In this manner, the tool blade is substantially prevented from being improperly angled during the resurfacing or resecting of the humeral bone **26** to form planar surface **50**.

Still further, it should be understood that humeral cut guide system **200** may include the curved connecting member **70**, which may extend away from upper surface **230** of cut guide plate **224** and connect cut guide plate **224** member with a patient-specific pin guide aperture **72** (see, e.g., FIG. **3**). The pin guide aperture **72** may be aligned per the specific patient and allows for passage of a drill, Steinmann pin, or guidewire (not shown), that allows humeral bone **26** to be reamed at the appropriate location for any desired resurfacing of humeral bone **26**.

Now referring to FIGS. **9** and **10**, another exemplary humeral cut guide system **300** is illustrated. Humeral cut guide system **300** includes a humeral cut guide member **302**. Humeral cut guide member **302** is configured to be patient-specific such that humeral cut guide member **302** mates with and nests in only one position on humeral bone **26**. In this regard, humeral cut guide member **302** includes a bone-engagement member **304** having a bone-engagement surface **306** that is complementary and made to substantially mate and nest in only one position (i.e., as a substantially negative or mirror or inverse surface) with a three-dimensional bone surface **62** of humeral bone **26** with or without associated soft tissues, which is reconstructed as a 3-D image via the aforementioned CAD or software.

As best illustrated in FIG. **9**, bone-engagement member **304** and bone-engagement surface **306** are specifically designed to mate and nest medially off of the proximal humeral bone **26**. In this regard, a bone-engagement member **304** is a curved member including an upper edge **308** located adjacent the distal portion of the greater tuberosity **63**, an opposing lower edge **310**, and side edges **312**. Bone-en-

gagement member **304** wraps about a portion of humeral bone **26** laterally from the distal portion of the greater tuberosity **63** in a direction toward bicipital groove **78**, and includes a first end **314** and a second end **316**. Extending from second end **316** is a cut guide plate **318** including an elongated slot **320**.

As best shown in FIG. **9**, cut guide plate **318** is unitary or connected to bone-engagement member **304** at a second end **316**. Cut guide plate **318** includes an upper surface **322** and a lower surface **324**, with elongated slot **320** positioned therebetween. Lower surface **322** defines a first tube-shaped aperture **326** that is configured to receive a drill (not shown) for drilling humeral bone **26**, and after drilling of the humeral bone **26**, is configured to receive a pin (not shown) that is operable to secure humeral cut guide member **302** to the humeral bone **26**. A second tube-shaped aperture **328** may also be formed at second end **316** that is configured to receive a drill (not shown) for drilling humeral bone **26**, and after drilling of the humeral bone **26**, is configured to receive a pin (not shown) that is operable to secure humeral cut guide member **302** to the humeral bone **26**. The above-noted configuration allows for nearly an entirety (i.e., at least 90%) of humeral head **26** to be exposed during the surgical procedure to allow the surgeon greater visual access to the humeral head **26**.

Although not illustrated, it should be understood that humeral cut guide system **300** may include the curved connecting member **70**, which may extend away from upper surface **322** of cut guide plate **318** and connect cut guide plate **318** with a patient-specific pin guide aperture **72** (see, e.g., FIG. **3**). The pin guide aperture **72** may be aligned per the specific patient and allows for passage of a drill, Steinmann pin, or guidewire (not shown), that allows humeral bone **26** to be reamed at the appropriate location for any desired resurfacing of humeral bone **26**. Alternatively, the curved connecting member **70** and pin guide aperture **72** may extend from upper edge **308** at a location positioned proximate first end **314**.

In addition, although cut guide plate **318** is illustrated as being spaced apart from humeral head **26**, it should be understood that cut guide plate **318** may be configured to abut humeral bone **26** during pre-operative design of humeral cut guide system **300**, if desired. By spacing cut guide plate **318** away from humeral head **26**, the unnecessary removal of soft-tissue (e.g., muscle, cartilage, etc.) from humeral head **26** is prevented, which assists in the patient's recovery after the arthroplasty. Further, although not required, lower surface **322** may extend outward relative to upper surface **320** such that a shelf or platform **98** (see FIG. **5**, described above) is formed. Platform **98** allows for a greater amount of surface area for the tool blade (not shown) to lie upon during resurfacing or resecting of the humeral bone **26**. In this manner, the tool blade is substantially prevented from being improperly angled during the resurfacing or resecting of the humeral bone **26** to form planar surface **50**.

Now referring to FIGS. **11** and **12**, another exemplary humeral cut guide system **400** according to an aspect of the present disclosure is illustrated. Humeral cut guide system **400** includes a ring-shaped patient-specific humeral cut guide member **402** that encircles the greater tuberosity **63** of the humeral head **26**. Humeral cut guide member **402** is patient-specific and includes a bone-engagement surface **404** that is complementary and made to substantially mate and nest in only one position (i.e., as a substantially negative or mirror or inverse surface) with a three-dimensional bone surface **61** of humeral bone **26** with or without associated soft tissues, which is reconstructed as a 3-D image via the aforementioned CAD or software. Although humeral cut guide member **402** is illustrated as being ring-shaped, it should be understood that humeral cut guide member **402** may be horseshoe-shaped (FIG. **13**), if desired.

Humeral cut guide member **402**, in addition to bone-engagement surface **404**, includes an upper surface **406** and a lower surface **408**. Extending radially inward and over humeral head **26** toward a center of humeral cut guide member **402** are a plurality of pie-shaped ribs **410**. Ribs **410** may include a wider proximal portion **412** unitary with humeral cut guide member **402** and a narrower distal portion **414**. Alternatively, ribs **410** may include the same width along the entire length thereof. Although only three ribs **410** are illustrated in FIGS. **11** and **12**, it should be understood that a greater or lesser number of ribs **410** may be used, without departing from the scope of the present disclosure. Regardless, spaces **411** between ribs **410** allow for easier viewing of humeral head **26** by the surgeon during the surgical procedure. In this regard, humeral cut guide member **402** is designed such that at least 50% of the humeral head **26** is exposed or visible when humeral cut guide member **402** is mated thereto.

The distal portions **414** terminate at a patient specific pin guide aperture **416**. Pin guide aperture **416** may be aligned per the specific patient and allows for passage of a drill, Steinmann pin, or guidewire (not shown), that allows humeral bone **26** to be reamed at the appropriate location for any desired resurfacing of humeral bone **26**. Pin guide aperture **416** includes an exterior surface **418** and a bone-engagement surface **420**. Bone-engagement surface **420** may be patient specifically designed pre-operatively. Further, although ribs **410** are illustrated as being spaced apart from humeral head **26**, it should be understood that ribs **410** may abut humeral head **26** with a patient specific bone-engagement surface as well.

A cut guide plate **422** is unitary or connected to humeral cut guide member **402** by a pair of connection members **424** such that cut guide plate **422** is spaced apart from humeral bone **26**. By spacing cut guide plate **422** away from humeral head **26**, the unnecessary removal of soft-tissue (e.g., muscle, cartilage, etc.) from humeral head **26** is prevented, which assists in the patient's recovery after the arthroplasty. Cut guide plate **422** includes an upper surface **426** and a lower surface **428**, with an elongated slot **430** positioned therebetween. Lower surface **428** defines a pair of tube-shaped apertures **432** that are configured to receive a drill (not shown) for drilling humeral bone **26**. After drilling of the humeral bone **26**, the tube-shaped apertures **432** are configured to receive a pin (not shown) that is operable to secure humeral cut guide member **402** to the humeral bone **26**. The above-noted configuration allows for a majority of humeral head **26** to be exposed during the surgical procedure to allow the surgeon greater visual access to the humeral head **26**.

Although cut guide plate **422** is illustrated as being spaced apart from humeral head **26**, which is desirable to preserve soft tissue as noted above, it should be understood that cut guide plate **422** may be configured abut humeral bone **26** during pre-operative design of humeral cut guide system **400**, if desired. Further, although not required, lower surface **428** may extend outward relative to upper surface **426** such that a shelf or platform **98** is formed. Platform **98** allows for a greater amount of surface area for the tool blade (not shown) to lie upon during resurfacing or resecting of the humeral bone **26**. In this manner, the tool blade is substan-

tially prevented from being improperly angled during the resurfacing or resecting of the humeral bone **26** to form planar surface **50**.

Moreover, although not illustrated in FIGS. **11** and **12**, it should be understood that humeral cut guide member **402** may include a registration member (see, e.g., the registration member **74** in FIG. **3**) similar to those described above. That is, humeral cut guide member **402** may include registration member (not shown) that extends away from humeral cut guide member **402** in a direction different from that ribs **410** including a bone-engagement surface **76** that is designed to mate and nest with the bicipital groove **78** of humeral bone **26**.

Now referring to FIGS. **14-20**, another exemplary humeral cut guide system **500** according to an aspect of the present disclosure is illustrated. Humeral cut guide system **500** includes a patient-specific humeral cut guide member **502**. Humeral cut guide member **502** is configured to be patient-specific such that humeral cut guide member **502** mates with and nests in only one position on humeral bone **26**. In this regard, humeral cut guide member **502** includes a bone-engagement member **504** having a bone-engagement surface **506** that is complementary and made to substantially mate and nest in only one position (i.e., as a substantially negative or mirror or inverse surface) with a three-dimensional bone surface **62** of humeral bone **26** with or without associated soft tissues, which is reconstructed as a 3-D image via the aforementioned CAD or software.

As best illustrated in FIG. **14**, bone-engagement member **504** includes an elongated primary member **508** extending in a first direction (i.e., a direction parallel with a coronal plane of the body) over humeral head **26**, including a pin guide aperture **510**. Pin guide aperture **510** is aligned per the specific patient and allows for passage of a drill, Steinmann pin, or guide wire (not shown), that allows humeral bone **26** to be reamed at the appropriate location for any desired resurfacing of humeral bone **26**. Bone-engagement member **504** also includes a pair of secondary members **512** extending substantially orthogonal to primary member **508**. Secondary members **512** define a portion of bone-engagement surface **506**, and assist in mating and nesting humeral cut guide member **502** in only one position on humeral bone **26** with or without associated soft tissues.

Bone-engagement member **504** also includes a registration member **514** that is patient-specifically sized and shaped to mate with the bicipital groove **78** of humeral bone **26**. Thus, registration member **514** is an elongated tab-shaped member having a proximal end **516** unitary or connected to bone-engagement member **504** and a distal end **518** located away from bone-engagement member **504**. With the primary member **508**, secondary members **512**, and elongated registration member **514**, humeral cut guide member **504** is configured to nest with humeral head **26** in a single position with as little material as possible. In this manner, a majority of humeral head **26** is exposed during the surgical procedure to allow the surgeon greater visual access to the humeral head **26**. In this regard, humeral cut guide member **502** is designed such that at least 60% of the humeral head **26** is exposed or visible when humeral cut guide member **402** is mated thereto.

Registration member **514** may also define a protrusion **520** that provides a curved contact surface **522** that allows humeral cut guide member **504** to be manipulated by the surgeon into correct alignment on the humeral bone **26**. In other words, the surgeon may place a finger-tip upon contact surface **522**, which allows the surgeon to more easily orient the humeral cut guide member **504** in a manner that bone-engagement surface **506** properly aligns with bone surface **62** of humeral bone **26**.

Humeral cut guide member **502** includes a cut guide plate **524** including an elongated slot **526**. As best shown in FIGS. **14**, **15**, **18**, and **19**, cut guide plate **524** is connected to bone-engagement member **504** with a tube-shaped member **528** that extends outward from registration member **514** such that cut guide plate **524** may be spaced apart from humeral head **26**. By spacing cut guide plate **524** away from humeral head **26**, the unnecessary removal of soft-tissue (e.g., muscle, cartilage, etc.) from humeral head **26** is prevented, which assists in the patient's recovery after the arthroplasty. Although tube-shaped member **528** extends outward from bone-engagement member **504** to an extent that cut guide plate **524** will be spaced apart from humeral head **26**, it should be understood, however, that the location of cut guide plate **524** may be adjusted along tube-shaped member **528** such that cut guide plate **524** may be moved closer to humeral bone **26**, if desired.

More specifically, cut guide plate **524** includes a connection portion **530** at an end **532** thereof that is configured to mate with tube-shaped member **528**. Further, connection portion **530** may include a mating aperture **534** that is designed to mate with one of a plurality of protrusions **536** formed along a surface **539** of tube-shaped member **528**. In this regard, connection portion **530** may be urged along tube-shaped member **528** to adjust the position of cut guide plate **524** relative to humeral head **26**. As connection portion **530** is urged along tube-shaped member **528**, the mating aperture **534** will mate with protrusions **536** such that connection portion **530** may be positioned at the selected protrusion **536**. Connection portion **530** may then only be moved when a force sufficient to disengage the mating aperture **534** from the selected protrusion **536** is provided to the connection portion **530**. In this manner, the position of cut guide plate **524** may be selectively adjusted based on the preferences of the surgeon during the shoulder arthroplasty. It should be understood that although cut guide plate **524** has been described above as being movable along tube-shaped member **528**, the present disclosure contemplates configurations where cut guide plate **524** is immovably fixed to tube-shaped member **528**.

As best shown in FIG. **16**, cut guide plate **524** includes an upper member **538** spaced apart from a lower member **540**, with elongated slot **526** defined by a gap **542** between upper member **538** and lower member **540**. Lower member **540** defines an elongated aperture **544** that is configured to receive a drill (not shown) for drilling humeral bone **26**. After drilling of the humeral bone **26**, a pin (not shown) such as a Steinmann pin or K-wire may be implanted in humeral bone **26**, which may be used to assist in positioning humeral cut guide member **502** relative to humeral bone **26**. In the illustrated embodiment, elongated aperture **544** travels parallel to tube-shaped member **528** to allow cut guide plate **524** to move along tube-shaped member **528** without interference from the pin (not shown). If cut guide plate **524** is immovable fixed to tube-shaped member **528**, however, it will be appreciated that elongated aperture **544** may extend in a non-parallel manner relative to tube-shaped member **528** to assist in securing cut guide member **502** to humeral bone **526**.

Although only a single elongated aperture **544** is illustrated in the figures, it should be understood that a pair of elongated apertures **544** may be used to allow for a pair of pins to be used to support a secondary cut guide (not shown) that is configured to assist in resecting or resurfacing of the

humeral bone **26** at a different angle in comparison to the angle defined by humeral cut guide member **502**. An exemplary secondary cut guide may be found in U.S. Ser. No. 14/265,577 assigned to Biomet Manufacturing, LLC. In this regard, after implantation of the pins, the humeral cut guide member **502** may be removed from humeral bone **26** with the pins remaining in place. The secondary cut guide may then be mated with the pins relative to the humeral bone **26**.

Although not required, lower member **540** may define a surface **546** that extends outward relative to upper member **538** such that a shelf or platform **548** is formed. Platform **548** allows for a greater amount of surface area for the tool blade (not shown) to lie upon during resurfacing or resecting of the humeral bone **26**. In this manner, the tool blade is substantially prevented from being improperly angled during the resurfacing or resecting of the humeral bone **26** to form planar surface **50**.

Lastly, as best shown in FIG. **20**, a support bar **550** may fix upper member **538** to lower member **540**. Support bar **550** is formed at an opposite end **552** of cut guide plate **524** relative to tube-shaped member **528**, and assist in maintaining the proper gap **542** between upper member **538** and lower member **540**. Notwithstanding, it should be understood that support bar **550** is removable during surgery by cutting support bar **550** with the saw or blade for resecting or resurfacing humeral bone **26**, as desired by the surgeon. It should be understood that although tube-shaped member **528** is illustrated as fixing cut guide plate **524** in one position relative to humeral head **26**, tube-shaped member **528** may be adjustable as illustrated in FIGS. **14-19**.

The foregoing description of the embodiments has been provided for purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosure. Individual elements or features of a particular embodiment are generally not limited to that particular embodiment, but, where applicable, are interchangeable and can be used in a selected embodiment, even if not specifically shown or described. The same may also be varied in many ways. Such variations are not to be regarded as a departure from the disclosure, and all such modifications are intended to be included within the scope of the disclosure.

What is claimed is:

1. A humeral cut guide member for a humeral head for a specific patient, the humeral cut guide member comprising:

a cut guide member comprising:

a body that is at least-partially ring-shaped to define an interior region, the body comprising a patient-specific inner surface; wherein the patient-specific inner surface is shaped to at least partially extend across a greater tuberosity of the humeral head for the specific patient

a patient-specific pin guide aperture disposed within the interior region, the patient-specific pin guide aperture being spaced from the body, wherein the patient-specific pin guide aperture defines a ring-shaped body having a bone-engaging surface; and

a plurality of ribs connecting the patient-specific pin guide aperture and the body to define a plurality of spaces between the body and patient-specific pin guide aperture, wherein ends of the ribs are spaced from the bone-engaging surface; and

a cut guide plate attached to the body.

2. The humeral cut guide member of claim **1**, wherein the ribs leave at least 50% of the greater tuberosity exposed within the interior region.

3. The humeral cut guide member of claim **1**, wherein the ribs are configured to place the patient-specific pin guide aperture in a patient-specific location on the greater tuberosity.

4. The humeral cut guide member of claim **1**, wherein the ribs extend from a narrow end at the patient-specific pin guide aperture to a wide end at the body.

5. The humeral cut guide member of claim **1**, wherein the ribs are curved such that the patient-specific pin guide aperture is spaced from the body along an axis of the patient-specific pin guide.

6. The humeral cut guide member of claim **1**, wherein the body defines a full ring configured to extend around the humeral head and across the greater tuberosity when the patient-specific pin guide aperture engaged the humeral head.

7. The humeral cut guide member of claim **1**, wherein the cut guide plate is attached to the body via a pair of connecting members.

8. The humeral cut guide member of claim **1**, wherein the cut guide plate comprises upper and lower surfaces that define a slot therebetween.

9. The humeral cut guide member of claim **1**, wherein the cut guide plate comprises a shelf.

10. The humeral cut guide member of claim **1**, wherein the cut guide plate comprises a tube-shaped aperture oriented toward the interior region.

11. The humeral cut guide member of claim **1**, further comprising a registration member extending from the body in a direction opposite the ribs, the registration member comprising a patient-specific bone-engaging surface.

12. A humeral cut guide member for a humeral head, the humeral cut guide member comprising:

a ring-shaped body that defines an interior region, the ring-shaped body configured to extend around the humeral head to encompass the greater tuberosity;

a pin guide ring disposed within the interior region;

a plurality of arcuate ribs connecting the pin guide ring and the ring-shaped body to define a hemi-spherical space; and

a cut guide plate attached to the ring-shaped body.

13. The humeral cut guide member of claim **12**, further comprising a registration member extending from the ring-shaped body away from the interior region, the registration member comprising a patient-specific bone-engaging surface.

14. The humeral cut guide member of claim **12**, wherein the ring-shaped body includes a gap so as to be non-continuous.

15. The humeral cut guide member of claim **12**, wherein the cut guide plate is attached to the ring-shaped body by a pair of connection members.

16. The humeral cut guide member of claim **12**, wherein the cut guide plate is arranged to guide a cut of the humeral head in a plane transverse to a central axis of the pin guide ring.

17. The humeral cut guide member of claim **12**, wherein the ring-shaped body comprises a patient-specific inner surface and the ribs position the pin guide ring in a patient-specific location in the interior region spaced from the ring-shaped body such that portions of the humeral head are visible between the ribs.

18. A humeral cut guide member for a humeral head for a specific patient, the humeral cut guide member comprising:

a cut guide member comprising:

a body that is at least-partially ring-shaped to define an interior region, the body comprising a patient-specific inner surface, wherein the patient-specific inner surface is shaped to at least partially extend across a greater tuberosity of the humeral head for the specific patient;

a patient-specific pin guide aperture disposed within the interior region, the patient-specific pin guide aperture being spaced from the body; and

a plurality of ribs connecting the patient-specific pin guide aperture and the body to define a plurality of spaces between the body and patient-specific pin guide aperture; and

a cut guide plate attached to the body.

19. The humeral cut guide member of claim **18**, wherein the body defines a fill ring configured to extend around the humeral head and across the greater tuberosity when the patient-specific pin guide aperture engaged the humeral head.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 11,801,064 B2
APPLICATION NO. : 17/157249
DATED : October 31, 2023
INVENTOR(S) : Kehres et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

On page 10, in Column 2, under "Other Publications", Line 23, delete "8, 2017"," and insert --28, 2017",-- therefor

In the Claims

In Column 13, Line 50, in Claim 1, delete "surface; wherein" and insert --surface, wherein-- therefor

In Column 13, Line 53, in Claim 1, delete "patient" and insert --patient;-- therefor

In Column 15, Line 16, in Claim 19, delete "fill" and insert --full-- therefor

Signed and Sealed this
Twenty-sixth Day of December, 2023

Katherine Kelly Vidal

Katherine Kelly Vidal
Director of the United States Patent and Trademark Office